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CONSUMER PRODUCT SAFETY COMMISSION'S REGULATION OF TRIS: THE NEED FOR AN EFFECTIVE CHRONIC HAZARDS PROGRAM

REPORT

together with

ADDITIONAL, SUPPLEMENTAL, AND SEPARATE VIEWS

BY THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
HOUSE OF REPRESENTATIVES
NINETY-FIFTH CONGRESS
SECOND SESSION

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LETTER OF TRANSMITTAL

House of Representatives,
Subcommittee on Oversight and Investigations,
Committee on Interstate and Foreign Commerce,
Washington, D.C., August 4, 1978.

Hon. Harley O. Staggers,
Chairman, Committee on Interstate and Foreign Commerce,
Washington, D.C.

Dear Mr. Chairman: The attached report by the Subcommittee on Oversight and Investigations on the Consumer Product Safety Commission's regulation of the toxic substance Tris, a flame retardant used in children's sleepwear, underscores the public need for an effective chronic hazards program for consumer products. Although Tris is no longer being used in children's sleepwear, it has by no means been totally eliminated as a hazard to the public health. Millions of Tris-treated garments are still being worn today and continue to pose a carcinogenic, mutagenic and teratogenic risk to children.

We recommend in this report that the Consumer Product Safety Commission take additional action to protect the public from this potential hazard.

This report highlights the Consumer Product Safety Commission's failure to make adequate use of the powers Congress gave it. We believe that Tris is merely one example of a far bigger problem confronting the agency, namely the regulation of chronic hazards in consumer products. We believe the Commission must be more forceful in its implementation of the Consumer Product Safety Act and the other transferred acts under its jurisdiction. Proper regulation of chronic hazards, a growing concern in our increasingly chemical-oriented society, can only be accomplished through a combination of full implementation of the law and proper programing and staffing.

We strongly recommend agency, interagency, and congressional action to accomplish this. The failure to improve the Commission's regulation of chronic hazards will continue to jeopardize the health of millions of Americans.

Sincerely,

John E. Moss,
Chairman, Subcommittee on Oversight and Investigations.

Attachment.

CONSUMER PRODUCT SAFETY COMMISSION'S REGULATION OF TRIS: THE NEED FOR AN EFFECTIVE CHRONIC HAZARDS PROGRAM

I. Introduction

By its 1972 enactment of the Consumer Product Safety Act (15 USC 2051 *et seq.*), Congress declared that government regulation was necessary to protect the public from "unreasonable risks of death, of injury or serious frequent illness associated with the use or exposure to consumer products."[1] The act created the Consumer Product Safety Commission (CPSC) and gave it responsibility for administering Federal programs designed to eliminate potentially dangerous consumer products.[2]

Although the Congress gave the Commission powerful tools with which to regulate consumer products, the Commission has often failed to use these powers fully.[3] The Commission has focused on the regulation of acute hazards such as lawn mowers and architectural glass. It has moved too slowly to develop a policy for chronic hazards in order to identify properly the appropriate actions the Commission should take concerning household products which present a carcinogenic, mutagenic, or teratogenic risk.

In this report, we examine the CPSC's actions concerning regulation of chronic hazards, and specifically, the Commission's regulation of Tris, (2, 3-dibromopropyl) phosphate[4] a carcinogen found in children's sleepwear. We will seek to analyze the following questions:

A. With regard to this specific case study—

1. Does the CPSC have adequate statutory authority to reduce exposure to Tris or other potentially toxic substances in consumer products?
2. Did CPSC properly and in a timely fashion investigate the potential danger posed by Tris in children's sleepwear?
3. Did CPSC take timely action to reduce consumer exposure to Tris or warn consumers of the possible risk posed by Tris in children's sleepwear after receiving information indicating that Tris might be hazardous?
4. Did CPSC take the most effective and timely action possible under the applicable statutes to ban Tris?
5. Did CPSC issue proper warnings on the potential hazard posed by already washed Tris-treated sleepwear?

B. With regard to CPSC's overall regulatory policy for chronic hazards—

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[1] H. Rept. No. 1153, 92d Cong., 2d sess., 21 (1972).

[2] Sec. 30 of the Consumer Product Safety Act (15 U.S.C. 2079) transferred the functions of the Secretary of Health, Education and Welfare under the Federal Hazardous Substances Act and the Poison Prevention and Packaging Act of 1970 to the CPSC and also transferred the functions of the Secretary of Commerce and the Federal Trade Commission under the Flammable Fabrics Act to the Commission. CPSC therefore administers today: Consumer Product Safety Act (15 U.S.C. 2051 et seq.); Federal Hazardous Substances Act (16 U.S.C. 1261 et seq.); Poison Prevention Packaging Act (15 U.S.C. 1471 et seq.); and, Flammable Fabrics Act (15 U.S.C. 1191 et seq.).

[3] "Federal Regulation and Regulatory Reform Report," Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 94th Cong., 2d sess., Oct. 1976, at 195.

[4] Throughout this report we will refer to the flame-retardant chemical Tris (2,3-dibromopropyl) phosphate of both the high volatile and low volatile quality, simply as "Tris."

1. Does CPSC have adequate statutory authority to establish a chronic hazards policy?
2. Is the establishment of a chronic hazards policy necessary to consumer safety?
3. Has CPSC established a chronic hazards policy governing products containing toxic substances which may present a carcinogenic, mutagenic or teratogenic threat to consumers?
4. Can CPSC make a meaningful contribution to the total government regulation of chronic hazards?

C. With regard to the children's sleepwear standard in particular—

1. Are the performance standards imposed by CPSC appropriate?
2. Should manufacturers placing flame-retardant chemicals in sleepwear be required to label the sleepwear with the name of the retardent used?

The report will also examine the role industry played in the Tris matter, and specifically, will review Michigan Chemical Co.'s (hereinafter referrred to as MCC) actions to test Tris for potential adverse effects and inform the public about the results of these tests.

II. Summary of Findings and Conclusions

The Subcommittee finds and concludes—

A. CONSUMER PRODUCT SAFETY COMMISSION

1. In handling the Tris matter:

(*a*) CPCS has sufficient statutory authority to protect the public from chronic hazards like Tris.

(*b*) CPSC failed to investigate the potential hazard posed by Tris, properly and in a timely fashion.

(*c*) CPSC failed to act in a timely fashion once information was received indicating that Tris posed a potential hazard.

(*d*) CPSC failed to take the most effective statutory action available to ban Tris-treated garments from the market in a timely fashion.

(*e*) CPSC failed to issue instructions to consumers which would protect them to the maximum extent feasible from the potential adverse effects of Tris in already washed, Tris-treated garments.

2. Further, the subcommittee finds that in regard to chronic hazard regulation:

(*a*) CPCS does have the authority to establish a chronic hazards policy.

(*b*) A chronic hazards policy can contribute to public protection and is essential to effectively regulate this type of hazard.

(*c*) CPSC has moved too slowly to establish such a chronic hazards policy.

(*d*) CPSC can contribute to public protection by regulating chronic hazards.

3. In regard to children's sleepwear regulation under the Federal Flammable Fabrics Act, the standards transferred from the Department of Commerce were outdated and inappropriate. The Commission should have acted with dispatch to modify these performance standards for children's sleepwear.

B. CONCERNING INDUSTRY HANDLING OF THE TRIS MATTER

1. Michigan Chemical Co. failed to adequately test Tris before recommending it for use in children's sleepwear.

2. Michigan Chemical Co. made misleading statements to the Commission and the general public, failed to disclose all the information it had in its possession on the toxicity of Tris, and failed to heed signs warning of the potential toxicity of Tris.

III. Summary of Recommendations

A. Congress should—

1. Provide resources for the development of a formal well-defined but limited CPSC chronic hazards evaluation program.

2. Consider legislation to amend the Toxic Substances Control Act (15 USC 2601 et seq.) section 4(e)(2)(A) to include on the Interagency TSCA Committee one member, appointed by the Chairman of the CPSC, who will have the same power as the Act (TSCA) (15 USC 2601 et seq.) section 4(e)(2)(A) to include on the Interagency TSCA Committee one member, appointed by the Chairman of the CPSC, who will have the same power as the other members of the committee.

B. The Consumer Product Safety Commission should utilize more fully their regulatory options—

1. In the case of Tris-treated children's sleepwear the CPSC should—

a. Declare Tris an imminent hazard and ban it under section 2(q)(2) of the Federal Hazardous Substances Act (FHSA).

b. Issue a warning to consumers stating that even after three washings Tris-treated children's sleepwear cannot be considered safe.

2. As part of its ongoing responsibilities the CPSC should—

a. Strengthen its regulation of Tris-type substances under FHSA, including carcinogens, mutagens, teratogens and other toxins by defining the term "toxic" to include any substance which causes cancers, mutagens or birth defects.

b. Develop "a surveillance program on potentially hazardous consumer products to support compliance action" as recommended by the National Academy of Sciences.

c. Develop internal staff capability to evaluate potential chronic hazards posed by consumer products.

d. Use the imminent hazard provisions more frequently.

e. Promulgate rules and to further define the term "imminent hazard" and the criteria to be considered before invoking "imminent hazard" powers.

f. Promulgate "summary judgment" rules to provide a basis for expediting hearings where little factual dispute exists.

g. Issue regulations implementing section 13 of the Consumer Product Safety Act.

h. Assure an increase in Flammable Fabrics Act Advisory Committee input into decisions and improve information flow to the committee.

i. Require that all chemically treated flame retardant sleepwear be labeled with the name of the chemical used.

C. Chemical Industry should—

1. Establish premarket screening programs designed to withhold from production potential carcinogens, mutagens, teratogens, and neurotoxins that may expose consumers to increased adverse health risks.
2. Carryout more chronic hazards testing.
3. Use the Ames test and/or other short-term mutagenicity tests to screen chemicals.

IV. METHODOLOGY

The subcommittee over the past 2 years has conducted an in-depth investigation into the adequacy of Federal regulatory efforts to reduce consumer exposure to potentially toxic substances in the environment. This investigation has covered subjects such as: Nitrosamines; [5] organic chemical contamination of drinking water; [6] toxic residues in meat and poultry; [7] adverse effects of Polybrominated Biphenyls (PBB's); [8] safety of hair dyes and cosmetic products; [9] and, pesticide contamination of food products.[10]

During the course of this investigation, the subcommittee has examined the adequacy of the statutes governing toxins and carcinogens administered by the Environmental Protection Agency (EPA), National Institute of Occupational Safety and Health (NIOSH), Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), Occupational Safety and Health Administration (OSHA), and Consumer Product Safety Commission (CPSC). This subcommittee's investigation of the Consumer Product Safety Commission's regulations of chronic hazards is part of this continuing evaluation of Federal regulation.

The subcommittee's investigation into the Tris matter, and CPSC's handling of chronic hazard problems in general, began in January 1976.[11] The initial work of the subcommittee resulted in 3 days of hearings: May 11, 13, and 16, 1977, on the issue of cancer-causing flame-retardant chemicals in children's sleepwear.[12] The main chemical discussed was Tris. On September 26, 28, 30 and October 3, 1977, the subcommittee held joint oversight hearings with the Consumer Protection and Finance Subcommittee on the Consumer Product Safety

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[5] "Environmental Causes of Causes of Cancer," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 94th Cong., 2d sess., ser. No. 94–141.

[6] "Carbon Tetrachloride Contamination of Public Drinking Water," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong.,1st sess., ser. No. 95–29.

[7] "Regulatory Reform—Volume II FPC and FDA," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 2d sess., Mar. 15 and 19, 1976, ser. No. 94–81.

[8] "Adverse Effects of Polybrominated Biphenyls (PBB's)," hearings before the Subcommittee on Oversight and Investigations Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 1st sess., ser. No. 95–65.

[9] "Hair dye and Cosmetic Product Safety," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong., 2d sess., Jan. 23, 26, and Feb. 2 and 3, 1978.

[10] "Cancer Causing Chemicals in Food," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong., 2d sess.' Feb. 14, 16, and 24, 1978.

[11] Letter to Hon. S. John Byington, Chairman, Consumer Product Safety Commission, from Hon. John E. Moss, chairman, Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Jan. 20, 1977.

[12] "Regulation of Cancer-Causing Flame-Retardant Chemicals and Governmental Coordination of Testing of Toxic Chemicals," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong., 1st sess., May 11, 13, and 16, 1977. (Hereinafter cited as *Hearings*.)

Commission.[13] During these hearings, the subcommittee examined further the Commission's regulation of chronic hazards.[14]

In addition to the above hearings, the subcommittee compiled and analyzed hundreds of pages of scientific and technical data received from the Commission, other government agencies, manufacturers of fire retardant chemicals,[15] consumer groups, and members of the scientific community.

V. THE CHRONIC HAZARD PROBLEM: THE SILENT HEALTH THREAT

We live today, in a chemical society. We ingest, inhale, and absorb through our skin numerous man-made chemical compounds, found in almost every product.

Most of these chemicals have been introduced into the environment only recently. The Council on Environmental Quality estimates that there are now 3.5 million known chemical compounds.[16] About 25,000 chemicals are in "significant production in the United States alone."[17] Approximately 1,000 new chemicals appear in marketed products each year.[18]

The Environmental Protection Agency (EPA) estimates that only about 6,000 of the 3.5 million chemicals now on the market have been tested for potential carcinogenicity.[19] Of the 6,000 tested, approximately 1,000 have induced tumors in laboratory animals.[20]

Dr. Lawrence Fishbein, in a report prepared for the Environmental Protection Agency, stated the following about the impact of this massive production of new chemicals:

> We do not know with precision what percentage of existing chemicals as well as those which enter the environment annually may be hazardous, primarily in terms of their potential carcinogenicity, mutagenicity, and teratogenicity. For example, although the etiology of human neoplasia, with rare exceptions, is unknown, it has been stated repeatedly that a large number of cancers can be attributed to environmental factors in proportions that can vary from 75 percent, to 80 percent, to 90 percent. Although these percentages can be disputed, the fact remains that a certain proportion of human cancers can be attributed to environmental factors, (for example, exposure to toxic chemicals, including: benzidine, 2-naphthylamine, 4-aminobiphenyl, 4-nitro-biphenyl, bis (chloromethyl) ether, vinyl chloride, auramine, chromium and inorganic arsenic).
>
> If estimates are correct that 60 percent or more of all human cancers are due to environmental agents, then about 500,000 cases per year may be involved. Exposure to chemical agents is known to cause a range of occupational cancers, mainly of the skin, bladder, lungs, and nasal sinuses. Recently, increased bladder cancer rates have been found in certain counties where chemical industries were concentrated. It is also projected that as the 20–30 year lag period for chemical carcinogenesis is almost over, a steep increase in the human cancer rate from suspect chemicals may soon occur.

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[13] "Consumer Product Safety Commission Oversight," hearings before the Subcommittee on Oversight and Investigations and the Subcommittee on Consumer Protection and Finance, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong., 1st sess., Sept. 26, 29, and 30; Oct. 3, 1977. (Hereinafter cited as *Oversight Hearings.*)

[14] Id. at 9–61.

[15] In February and April, 1977, the subcommittee sent a series of letters to over 15 producers of flame-retardant chemicals and more than 10 major consumers of flame-retardant products produced between 1967 and 1977; largest consumers of flame-retardant chemicals; type of products and name of products containing flame-retardants; what information manufacturers of flame-retardant had on potential health effects and environmental effects of these chemicals.

[16] Environmental Quality 1977: The Eighth Annual Report of the Council on Environmental Quality, Council on Environmental Quality, December 1977, at 4.

[17] "Potential Industrial Carcinogens and Mutagens," Lawrence Fishbein, Office of Toxic Substances, Environmental Protection Agency, Washington, D.C., May 5, 1977, at 1. (Hereinafter cited as *Fishbein Report.*)

[18] Carbon Tetrachloride Contamination of the Ohio River: A Case Study of Federal Efforts to Ensure the Availability of Safe Drinking Water," report by the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong., 1st sess. September 1977.

[19] *Fishbein Report,* supra note 17, at 1.

[20] Id.

Concomitant with the potential cancer risk of environmental agents, is the growing concern over the possibility that future generations may suffer from genetic damage by mutation-inducing chemical substances to which large segments of population may unwittingly be exposed.[21]

The need to consider the potential for genetic damage from chemicals is becoming increasingly important. During congressional considerations of the Toxic Substances Control Act (15 USC 2061 et seq.), the National Foundation—March of Dimes pointed out that:

> More than 200,000 infants are born with physical or mental damage each year, a staggering 7 percent of all births * * *. A total of 15 million Americans have birth defects serious enough to drastically affect their daily lives * * *. It is with alarm that our attention is drawn to some aspects of modern technology which work counter-productive to our aims. Each year billions of pounds of chemicals which are virtually untested and unregulated are produced in industrial processes and used in commercial products. Experience with vinylchloride has shown it to be a highly toxic substance which experimentally can cause cancer and birth defects; but this experience came only with its burden of proof on the public.[22]

Although the subcommittee believes that many of these chemicals have enhanced the quality of products, the impact of this wide scale production of substances previously nonexistent on human health and the environment remains unknown. Unfortunately, in many cases, the destructive qualities of some of the chemical compounds have not been discovered until they have caused significant human harm.[23]

There are four Federal regulatory agencies with principal responsibility for protecting the public from unnecessary exposure to potentially dangerous toxic substances. They are: Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OHSA), Food and Drug Administration (FDA), and the Consumer Product Safety Commission (CPSC). Although the Consumer Product Safety Commission is one of the smallest of these agencies—$39 million versus $849 million for EPA, $294 million for FDA, $139 million for OHSA, its responsibility for regulation of toxic substances in consumer products is significant.[24]

The Consumer Product Safety Act directs the Commission: "To protect the public against unreasonable risks of injury associated with consumer products." [25] Since there are over 15,000 consumer products within the scope of the Commission's jurisdiction, and because some of these products may contain chemicals posing an "unreasonable risk of injury" to consumers through either acute or chronic exposure, the Commission is responsible for examining the use of products containing potentially dangerous chemicals.

Furthermore, the Commission is not only responsible for protecting consumers from unreasonable risks, it is also responsible for educating them about the safety of products and investigating the causes and prevention of injury.[26] The purposes of the CPSA include:

> To assist consumers in evaluating the comparative safety of consumer products [and]

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[21] Id. at 1–2.

[22] "Toxic Substances Control Act," report of the Senate Committee on Commerce, 94th Cong., 2d sess., Mar. 16. 1976.

[23] Several human carcinogens such as benzidine, 2-naphthylamine, 4-amino biphynel vinyl chloride, chromium and inorganic arsenic were not discovered as human carcinogens until after workers exposed to these chemicals developed cancer.

[24] Justification of appropriation estimates for Committee on Appropriation, U.S. House of Representatives, fiscal year 1979.

[25] 15 U.S.C. 2051.

[26] Id.

> To promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.[27]

This report will focus on the Consumer Product Safety Commission's efforts to regulate one toxic chemical in children's sleepwear: Tris. It will also evaluate how the Commission handled the Tris matter within its available powers.

VI. Consumer Product Safety Commission's Handling of the Tris Matter

A. EARLY BACKGROUND OF THE SLEEPWEAR STANDARD

The Federal Flammable Fabrics Act (15 USC 1191, *et. seq.*) required that the Department of Commerce develop standards to further reduce the injuries, deaths and property damage resulting from fabric-related fires, the Department of Commerce began in the early 1970's to issue regulations establishing national flammability standards for a variety of consumer products. The Commerce Department established standards for carpets, rugs, mattresses and children's sleepwear.[28]

Standards for the flammability of children's sleepwear were promulgated in 1971 by the Department of Commerce for sizes 0–6x, and in 1974 for sizes 7–14 by the Consumer Product Safety Commission. These standards required that all children's sleepwear garments sold in interstate commerce pass a reproducible flame retardancy test developed by the National Bureau of Standards (NBS).[29] This test, which is designed to evaluate the potential flammability of the garment is a performance test and, therefore, does not mandate that manufacturers utilize any specific type of treatment, design, or fabric. Nevertheless, the requirements of the test meant that many fabrics could not pass without chemical treatment.[30] The standards did not, however, require that manufacturers determine whether the chemical, or fabric used produces either acute or chronic toxic effects on consumers.

Cotton, which had until the early 1970's comprised approximately 85 percent of all children's sleepwear fabrics, began rapidly to lose its prominence in this market for two reasons.[31] First, untreated cotton fabrics could not meet the flammability standards. Second, the cotton-treated products which passed the flammability tests were not desired by consumers.[32]

Polyester, acetate, triacetate, and mixtures of man-made fibers quickly became the fabrics of choice. These fabrics could be easily treated with chemicals and unlike the treated cotton products, the final products were acceptable to consumers.

Textile mills began in 1971 to develop technologies for "padding on" chemical flame-retardants for woven and knit polyester sleepwear.[33] By 1973, a large market was developing for flame-retardant chemicals like Tris. Tris, because of its ability to adequately and inexpensively flame retard numerous man-made synthetic fabrics, became the chemical most widely used.

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[27] Id.

[28] 16 CFR 1602 subch. det. sec. (1632.63).

[29] 16 CFR 1615.

[30] *Hearings*, supra note 12, at 284.

[31] Id. at 313.

[32] Id. at 91.

[33] Id. at 92.

Production of Tris quadrupled between the years 1971 to 1974. In 1971, approximately 3 million pounds of Tris were produced.[34] The expanded production of Tris was related, at least in part, and its expanded use as a flame-retardant in children's sleepwear. Michigan Chemical Co., the major producer of Tris, began to promote actively the use of Tris in children's sleepwear in 1974.

When the children's sleepwear standards were under development, both manufacturers and government officials were aware that industry might be required to utilize chemical treatment for meeting the standards.[35] However, long-term chronic toxicity tests were not conducted, by either the Government or the chemical industry on chemicals proposed for use in sleepwear.[36] Although some questions were raised about the potential danger of using untested chemicals in these garments, no effort was made to adjust the standard to assure that untested chemicals were not used.[37]

B. CPSC IGNORED WARNING SIGNALS

Individuals in the Commission's Bureau of Biomedical Sciences (the Bureau responsible for determining whether a product poses an unreasonable toxicological threat to consumers) raised questions about the safety of flame-retardant chemicals in fabrics as early as July 1973.[38]

In a memorandum entitled "Project Title: Flame Retardant Chemicals," Dr. E. P. Mazzola of the Bureau of Biomedical Sciences, requested funds to conduct a study on flame-retardant chemicals.

Dr. Mazzola wrote:

> This study would determine the contact conditions under which flame retardants are removed from various fabrics and identify the degradation products. If such processes were shown to be potentially harmful to the general public, then the specific degradation or extraction products responsible for these adverse effects, would already be identified and could then be tested individually to determine which one or ones were dangerous.[39]

This project was never funded.[40]

Information indicating that the use of at least one flame retardant might raise safety questions was brought to the Commission's attention in the same year that Tris was placed on the National Cancer Institute's (NCI) cancer bioassay test list by the Chemical Selection Workgroup.[41] Tris was suggested as a candidate for long-term animal feeding tests because of its suspicious chemical structure and its growing use as a fabric flame retardant. CPSC did not determine in 1974 or 1975 why Tris was placed on this list or how much Tris was incorporated into consumer products.[42]

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[34] The textile industry was aware that chemical treatment might pose problems and in remarks at the Department of Commerce hearings on the sleepwear flammability standards in 1971, nine trade organizations endorsed the following statement:

> It would be a grave mistake and a serious setback for progress in fire resistant textiles if, through hasty action, large numbers of children were exposed to fabrics which caused skin rashes and other allergic or toxic reactions. *Hearings*, supra note 12, at 275.

[35] *Hearings*, supra note 12, at 277.

[36] The subcommittee's review of all the materials presented suggests that no chronic toxicity test had been conducted on flame-retardant chemicals being suggested in 1971 for use in children's sleepwear.

[37] *Hearings*, supra note 12, at 277.

[38] Project Narrative Memorandum on Flame Retardant Chemicals by Dr. E. P. Mazzola, Bureau of Biomedical Sciences, CPSC, July 9, 1973.

[39] Id.

[40] *Hearings*, supra note 12, at 388.

[41] Id. at 372.

[42] Id.

In 1974, 2-year animal feeding studies were begun on Tris under a National Cancer Institute contract to determine whether Tris was a carcinogen. Although Tris-treated sleepwear was becoming more prevalent, the Commission took no steps to further identify the brand-name products containing Tris, the amount of Tris padded on these products, or the amount which might be available to children through either ingestion or absorption.

Between 1973 and October 1975, no action was taken by the Commission to further investigate the potential danger posed by Tris-treated garments.[43] The Commission monitored the progress of the NCI tests, but it did not request that NCI expedite the testing until October 1976, after CPSC had received outside pressure in the form of a public request by the Environmental Defense Fund to expedite Commission action on EDF's petition to place a warning label on Tris-treated garments.[44]

C. OUTSIDE TEST DATA AVAILABLE

Nearly all the information on the potential health hazard posed by Tris came from outside the Commission.

The first significant evidence concerning the potential health hazard posed by Tris was transmitted to the Commission on October 29, 1975, via letter from Glenn E. Schweitzer, Director of the Office of Toxic Substances, Environmental Protection Agency (EPA), to Stanley Parent, Acting Executive Director of CPSC.[45] The letter informed the Commission that Dr. Herbert Rosenkranz, who had been conducting research on several chemical compounds for EPA, had found Tris "capable of inducing mutations in *salmonella typhimurium*" when tested by the "Ames plate incorporation assay." [46]

The "Ames plate incorporation assay" (Ames test) is a simple, inexpensive and highly sensitive test for mutagenicity. Mutagenicity is "the power to alter the structure of DNA (to a greater or lesser extent), thus inflicting a potential metabolic aberration in which the growth of cells runs out of control." [47] The Ames test identifies substances which should be considered as causing possible mutagenic changes in man.

The Ames test is also valuable as a screening test for chemicals which may be human carcinogens. Application of the Ames test has shown that 90 percent of the 174 known human and animal carcinogens are also mutagens.[48] A positive finding of mutagenicity under the Ames test should lead to the presumption that the chemical is also a carcinogen and, therefore, should be the subject of additional confirmatory testing.

The Ames test also makes it possible to rate the mutagenic potency of the substance under test.[49] Tris, for example, was found to be a very potent mutagen, more potent than a number of known cancer-causing substances.[50]

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[43] The Commission's "History of the Tris Issue" does not indicate that the Commission took any action during this time frame. Moreover, a review of Commission memorandum in Tris clearly indicates that action was taken.

[44] The Commission, on Nov. 8, 1976, requested via letter to Dr. Frank J. Rauscher, National Cancer Institute, that NCI accelerate its work to finalize its testing of Tris. This action was taken following the transmission to the Commission of a petition from the Environmental Defense Fund (Oct. 21, 1976) to give its Mar. 24, 1976, petition expeditious consideration.

[45] Letter from Glenn E. Schweitzer, Director, Office of Toxic Substances, EPA, to Stanley R. Parent, Executive Director, CPSC, Oct. 29, 1975.

[46] Id.

[47] Dr. Roger Lewin, "Cancer Hazards in the Environment," New Scientist, Jan. 22, 1976, at 178.

[48] B. N. Ames, J. McLann, and E. Yamasaki, Mutation Research, 31 (1975), 347.

[49] Note 49, *supra* at 169.

[50] Arlene Blum and Bruce N. Ames, "Flame-Retardant Additives as Possible Cancer Hazards," Science, vol. 195, Jan. 7, 1977, at 19.

Between October 1975 and late March 1977, the Commission rereported that it gathered information on "Tris and other flame retardants." [51] Among other things, the Commission received information in this time period confirming the Rosenkranz findings.

On March 19, 1976, Dr. Robert Hehir, Director of the Bureau of Biomedical Sciences, in a telephone conversation with Dr. Bruce Ames, was informed that Ames, based on his extensive testing of the chemical, believed Tris was not only a mutagen but also a carcinogen.[52] In this conversation, Ames suggested that the Commission ban the use of Tris in consumer products, especially children's sleepwear.[53] Ames concerns were noted, but not acted upon.[54]

The Commission's inaction on this problem generated the filing of a petition on March 24, 1976, by the Environmental Defense Fund, Inc. (EDF), a private non-profit environment and health safety group, requesting that the Commission promulgate a rule:

> Requiring a label on sleepwear [containing Tris] warning consumers of the potential hazard and recommending that sleepwear be pre-washed three times prior to use, a practice which would reduce, although not eliminate, the exposure.[55]

The EDF petition also stated that large amounts of Tris could be found on the surface of unwashed, treated children's sleepwear.[56]

The petition cited several scientific studies which concluded that absorption of Tris through the skin of rats was significant.[57] EDF suggested that since large amounts of Tris could be found on the surface of garments, children could easily ingest a significant amount of the chemical through skin absorption and/or mouthing. Prolonged exposure to these levels of Tris, EDF contended, could result in a substantial health risk.[58]

While the Commission was deciding what action to take on the EDF petition, Tris-treated garments continued to be sold. Although some textile and garment manufacturers began to look for substitutes for Tris,[59] without a ruling on its safety there was no incentive to switch to other chemicals or fabrics.

In July of 1976, while CPSC was examining the EDF petition, it received a memorandum from the Michigan Chemical Co., the major manufacturer of Tris, challenging EDF's statements about the potential safety hazard posed by Tris.[60] Michigan Chemical Co. widely distributed this memorandum to its customers. Although the Commission refused public comment on the memorandum, a CPSC staff member concluded after reviewing the document that it was both misleading and scientifically unmerited. The staff review stated:

> The memorandum claims (Michigan Chemical Co. memorandum), "Tris does not pose a mutagenic or carcinogenic hazard." Clearly this statement is scientifically unmerited. Certainly enough evidence now exists to raise suspicions as to such risk. Inclusion of such an unjustifiable claim in this document raises questions as to the objectivity of the entire memorandum.[61]

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[51] *Hearings*, supra note 12, at 372.

[52] Memorandum of Telephone Conversation of Mar. 19, 1976, between Dr. Bruce Ames and Dr. Robert Hehir, Director, Bureau of Biomedical Sciences, CPSC, (prepared by Dr. Hehir), Mar. 23, 1976.

[53] Id.

[54] There is no indication in the record of Commission actions that they acted on Dr. Ames letter.

[55] Petition pursuant to 15 U.S.C. 2059 to the CPSC to commence a proceeding for the issuance of a consumer product safety rule. Mar. 24, 1976, at 1.

[56] Id. at 5.

[57] Id. at 6.

[58] Id. at 2.

[59] Internal memorandum from Julia Clones to Albert S. Dimcoff, CPSC, Aug. 6, 1976.

[60] Memorandum for the U.S. Consumer Product Safety Commission on the safety of the flame-retardant chemical tris, Michigan Chemical Co., July 12, 1976.

[61] Memorandum from Dorothy Carter to Robert Hehir entitled "Review of Michigan Chemical Company Memorandum," Bureau of Biomedical Sciences, CPSC, July 21, 1976, at 3.

Since the Commission did not publicly criticize the Michigan Chemical Co. memorandum, textile mills using Tris as a flame retardant for fabrics in children's sleepwear were not made aware of the Commission staff's questions challenging the scientific merit of Michigan Chemical Co.'s position. The consuming public also was not made aware of the questions CPSC raised internally.

On October 20, 1976, more than 6 months after the filing of the original petition, EDF requested that the Commission expedite consideration of its petition.[62] In a letter to EDF dated December 21, 1976, Commission Secretary Sadye E. Dunn indicated that the Commission had taken no regulatory action and did not believe that "an unreasonable period of time" had elapsed since the petition was filed.[63] Dunn indicated, however, that the staff had undertaken an exhaustive search and review of available literature and that Chairman Byington had written to the National Cancer Institute concerning the status of rat and mouse studies on Tris. The letter concluded that CPSC would take no action until the NCI animal feeding carcinogenicity study data was available.[64]

Also, in October 1976, the Commission staff received additional health hazard information on Tris from the Food and Drug Administration (FDA). Included in an October 20, 1976, letter from Dr. Michael Prival of FDA to Dr. Robert Osterberg, CPSC, were results of three new studies on Tris.[65] According to the letter these studies demonstrated that:

> (1) * * * Tris can cause reparable breaks in DNA strands of human cells grown in culture; (2) * * * Tris causes unscheduled DNA synthesis in human cells in tissue culture; and (3) * * * at one dose, Tris induced heritable mutations (sex-linked recessive lethals) in *Drosophila melanogaster*.[66]

These studies were reviewed by Dr. Joseph McLaughlin of the Commission's Bureau of Biomedical Sciences. On November 18, 1976, Dr. McLaughlin wrote a memorandum to Dr. Robert Hehir, Chief of the Division of Biomedical Sciences, concluding that Tris could not be considered safe. Dr. McLaughlin wrote:

> In conclusion, it is my considered judgment *that children's sleepwear containing Tris cannot be considered safe* based on all the data now available and *I would consider it prudent for such garments to be treated so as to prevent unsafe chemicals from being available for deleterious effects to children* using such sleepwear containing Tris. [Emphasis added.] [67]

McLaughlin's conclusion did not meet with Dr. Hehir's approval and in a return memorandum Hehir directed McLaughlin to rewrite his November 18, 1976 memorandum.[68]

The same material reviewed by Dr. McLaughlin was also officially transmitted to the Commission on November 16, 1976,[69] with a letter of explanation from Dr. Robert Harris of EDF. The EDF letter was transmitted to Dr. Hehir for further analysis by Francine Shacter, on

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[62] Motion for an expeditious consideration of petition for the issuance of a consumer product safety rule. before the U.S. CPSC, Oct. 20, 1976.

[63] Letter from Sedye E. Dunn, Commission Secretary, CPSC, to Phillip J. Mause and Dr. Robert H, Harris, EDF, Dec. 31, 1976.

[64] Id.

[65] Letter from Dr. Michael J. Prival, FDA, to Dr. Robert Osterberg, CPSC, Oct. 26, 1976.

[66] Id.

[67] Memorandum from Dr. Joseph McLaughlin to Dr. Robert Hehir, Bureau of Biomedical Sciences, CPCS, Nov. 18, 1976, at 1.

[68] Memorandum from Dr. Robert Hehir to Dr. Joseph McLaughlin, Bureau of Biomedical Sciences, CPSC, Nov. 23, 1976, at 2.

[69] Letter from Dr. Robert Harris, EDF, to Mrs. F. Shacter, CPSC, Nov. 17, 1976.

November 23, 1976. Hehir rejected EDF's comments on these new studies.[70]

Besides the possibility that Tris was itself a hazardous substance, some scientists believed that Tris compounds were contaminated with *Dibromochloropropane* (DBCP). Questions about Tris contamination with the chemical DBCP were first raised with the Commission in November 1976. McLaughlin in his second memorandum reacting to Hehir's criticism of his November 18 memorandum, wrote the following about DBCP contamination of Tris:

> In regard to DBCP, I consider it a proven carcinogen in mice and rats. The early production of both squamous cell carcinoma and mammary tumors in mice and rats would in my opinion make it of very serious concern if children ingested it from Tris-treated sleepwear.
>
> * * * * * * *
>
> The data needed is how much DBCP may actually be available for ingestion by children using Tris-treated sleepwear *I would seriously doubt it is zero.* [Emphasis added.][71]

McLaughlin pointed out in his memorandum that Kerst had found that Tris samples contained 0.05 percent DBCP.[72] McLaughlin further observed that CPSC should immediately determine the DBCP content of Tris and therefore the amount of DBCP which might be ingested or absorbed by children wearing Tris-treated garments.

Additional information on the potential hazard of DBCP in children's sleepwear was brought to Hehir's attention by the Director of Chemical Analysis for CPSC, Gale D. Wyer, in a November 30, 1976, memorandum.[73] Wyer stated:

> The studies on DBCP seem (again to a chemist) to indicate that DBCP is a carcinogen in the rat and mouse and thus presumably DBCP poses a carcinogenic hazard to the human.[74]

Wyer stated further that:

> I do not feel that the presence of a known carcinogen can be tolerated in a consumer product.[75]

Hehir responded in a December 3, 1976, memorandum stating that:

> Based on the Olsen study with DBCP it is clear that this chemical is capable of causing cancer in laboratory rodents. We would be concerned about *substantial* quantities of this chemical in consumer products wherein *substantial* exposure is likely. [Emphasis added.][76]

Hehir further attacked Dr. McLaughlin's memorandum of November 18, 1977, in his memorandum. He stated that McLaughlin's conclusion that "children's sleepwear containing Tris cannot be considered safe based on all the data" was unsupportable.[77] He wrote "There is no evidence to show or support this allegation." [78] Dr.

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[70] Memorandum from Dr. Robert Hehir to Francine Shacter, CPSC, Nov. 24, 1976.

[71] Memorandum from Dr. Joseph McLaughlin to Dr. Robert Hehir, (Response to memorandum date Nov. 18, 1976), Bureau of Biomedical Sciences, CPSC, Nov. 30, 1976, at 2.

[72] Id at 2.

[73] Memorandum from Gale D. Wyer, to Dr. Robert M. Hehir, Bureau of Biomedical Sciences, CPSC, Nov. 30, 1976.

[74] Id at 2.

[75] Id.

[76] Memorandum from Dr. Robert M. Hehir to Michael Brown, Acting Executive Directive, CPSC, Dec. 3, 1978, at 1.

[77] Id. at 2.

[78] Id.

Hehir concluded that the Commission should continue to wait until the NCI studies were complete before taking action on Tris.[79]

The Commission did not receive preliminary data from the National Cancer Institute until February 4, 1977, although these data were available as early as December 29, 1976.[80] The data indicated that Tris was a carcinogen in both rats and mice.[81]

On February 8, 1977, the Environmental Defense Fund petitioned the Commission to ban Tris containing children's sleepwear as an "imminent hazard to the public health" under the Federal Hazardous Substances Act.[82] EDF stated in its petition that "based on the results of the NCI Bioassay Study, Tris must now be considered a potent carcinogen and a carcinogenic risk to humans." [83]

EDF pointed out that CPSC had at least two alternative avenues of action:

> (1) to file an action in United States District Court based upon a finding that wearing apparel treated with Tris is an "imminently hazardous consumer product" (15 USC § 2061);
>
> (2) to promulgate applicable consumer product safety rules under 15 USC § 2057 and 2058.[84]

In addition EDF asked the Commission to:

> Investigate, together with other agencies, if necessary, the environmental and health effects of various ways of disposing of the current stock of Tris garments—including both unsold garments and those already in the possession of consumers—and promptly develop a plan for such disposal which minimizes environmental and health risks;
>
> Issue pursuant to 15 U.S.C. § 1272 a general warning to the public that Tris-treated wearing apparel will contain residual amounts of Tris throughout the life of the garment, inform the public about how to determine which garments they presently possess are Tris-treated, and urge the public to dispose of these garments consistent with the disposal plan developed by CPSC;
>
> Establish standards and protocols for the investigation by industry of the health effects (including carcinogenic and neurotoxic) of the alternatives to Tris and require labeling of garments containing flame retardant additives for which such testing has not been completed stating that "the toxic properties of the flame retardant chemical(s) used in this product have not been evaluated; and
>
> Consider a modification of the sleepwear standards FF3–71 and possibly FF5–74, to allow sale of 100 percent polyester and blends of polyester with acetate or triacetate without chemical additives.[85]

On March 23, 1977, EDF apparently concerned that the Commission had not taken action on its February 8 petition, initiated a law suit "seeking an immediate Commission ban on the sale of Tris-treated garments." [86]

D. REGULATORY ACTION TO BAN TRIS

The Commission took no action on EDF's February 8 petition until April 7, 1977. At that time, the Commission decided to make its interpretation that children's sleepwear containing Tris were "banned hazardous substances" under section 2(q)(1)(A) of the Federal Hazardous Substances Act. The ban was published in the Federal Register the next day.[87]

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[79] Id.

[80] A preliminary computer printout indicating the results of the NCI feeding study on rats and mice was available in the form of "animal tumor data" in early January 1977.

[81] Bioassay of Tris (2,3-dibromopropyl) phosphate for possible carcinogenicity, case No. 126-72-7, National Cancer Institute.

[82] Petition of the Environmental Defense Fund to Ban the Sale of Tris-treated Wearing Apparel, before the U.S. Consumer Product Safety Commission, Feb. 8, 1977.

[83] Id. at 10.

[84] Id. at 16.

[85] Id. at 19-20.

[86] *Environmental Defense Fund et. al.* v. *Consumer Product Safety Commission*, Civil No. 77-517 (D.D.C. filed Mar. 23, 1977).

On April 8, 1977, EDF "amended its complaint in its March 23 lawsuit to seek the repurchase of Tris-treated products sold to consumers prior to April 8 and already washed, and also seeking Commission action against adult Tris-treated wearing apparel." [88]

The Commission's April 7, 1977 ban created confusion. Numerous legal actions were undertaken to halt and modify it.[89] The ban was extended to Tris, all fabrics, yarns, and fibers that contain Tris, and all garments made from such fabrics, yarns and fibers that were intended for use in the manufacture of children's wearing apparel. Finally, on December 6, 1977 two notices of clarification were printed in the Federal Register. One withdrew the Commission's "two previously published interpretations concerning Tris products because they (had) been misconstrued." [90] The other notice, contained a Commission statement of policy. The statement declared, in part, that:

> The Commission continues to believe that the Tris products named in the April 8 and June 1 Federal Register documents are "banned hazardous substances" within the FHSA definition of this term (15 U.S.C. 1261(q)(1)(A). Since the publication of the Commission's April 8 and June 1 Federal Register documents, additional scientific information has strengthened and reinforced the Commission's belief that these Tris products are banned hazardous substances. The Commission's intent is to file individual enforcement actions to prevent the sale and to require the statutory repurchase of such products, according to the applicable provisions of the FHSA (15 U.S.C. 1263, 1264, 1265, 1267, and 1274).[91]

The Commission continued to attempt to enforce a policy classifying Tris-treated children's sleepwear were "banned hazardous substance." Attempts at enforcement were being thwarted by the courts. A June 23, 1977, U.S. district court opinion and a February 1978 U.S. district court opinion basicallly state that the Commission did not act appropriately and violated the constitutional rights of affected parties by denying them due process. Further discussion of the Courts objections to CPSC's actions can be found in chapter VIII.

To date, the Commission has not acted on all provisions of the February 7, 1977, EDF petition. It rejected the EDF request that it warn consumers about the potential threat from Tris-treated garments which had already been washed. Moreover, it declared that after three washings consumers should consider Tris-treated garments safe.[92] This conclusion was challenged by several scientists appearing before the subcommittee in May 1977. Witnesses before the subcommittee indicated that no amount of washing could guarantee that the garments were safe.

> Mr. WAXMAN. I want to ask all the members of the panel for their opinions as to whether numerous washings of Tris treated children's sleepware will eliminate the health risk to children?
>
> The Consumer Product Safety Commission has contended that three washings will eliminate the risk.
>
> Is the Commission's statement one with which all of you could agree?

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[87] 42 F. R. 18850-18852 (1977).

[88] Note 86, supra.

[89] "Actions by the Consumer Product Safety Commission Involving Tris," CPSC, March 1978.

[90] 42 F.R. 61621 (1977).

[91] 42 F.R. 61622 (1977).

[92] *Hearings*, supa note 12, at 398.

Dr. AMES. The standards require that the garment has to undergo 50 washings and still be flame proof. They are using chemicals that won't get washed out in the washing machine.

They can be extracted out with a solvent but they would not use it if it could be washed out. Really when people talk about washing out, they are talking about the surface material.

I think, at least in this case, that chemical diffusing out from the inside of the fibers may cause it to be impossible to get rid of all that surface material.

Mr. WAXMAN. Would any of you recommend as the Commission has suggested, that parents continue to use Tris treated garments after three washings?

Dr. KAY. No.

Dr. AMES. No.

Dr. HARRIS. No.

Mr. RAUCH. No.

Dr. KAY. Not even after 50. After 40, occluded material comes out due to the heat. It keeps coming out of the center of the fiber to the surface.[93]

Furthermore, the Commission has taken action on only one other request in the EDF petition: modification of the sleepwear standards. On October 20, 1977, the Commission published in the Federal Register final rules modifying the standards for the flammability of children's sleepwear sizes 0–6x and sizes 7–14.[94] On February 2, 1978, CPSC announced that two amendments would be made to the Sleepwear standards.[95] One would eliminate the residual flame time (RFT) test requirement and criteria. The other modifies trim testing. The Commission issued final regulations on February 6, 1978, and these regulations became effective immediately.[96]

VIII. FINDINGS AND CONCLUSIONS

A. Consumer Product Safety Commission (CPSC)

1. HANDLING OF THE TRIS MATTER

(*a*) CPSC has sufficient authority to protect the public from chronic hazards like Tris.

(i) *CPSC can gather information of the potential hazard of Tris*

Information could have been made available to the CPSC at an earlier date making it possible for the CPSC to assess the potential hazard posed by Tris well before April 1977.

The CPSC could have taken full advantage of its regulatory powers to assist the CPSC's Bureau of Biomedical Sciences in gathering information about the potential hazard posed by Tris. Under section 27(b)(1) of the CPSA, the CPSC may by order require "any person to submit in writing such reports and answers to questions as the Commission may prescribe;" (in addition, the CPSC could have, by rule, collected performance and technical data as related to the safety of a product under section 27(e) of the CPSA).[97]

The CPSC by fully utilizing its regulatory powers could have required Michigan Chemical Co. to supply chronic toxicity data as early as 1974.

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[93] Id. at 83–84.

[94] 42 F.R. 56568–56572 (1977).

[95] News release, CPSC, "CPSC Issues Sleepwear Amendments," Feb. 2, 1978.

[96] 42 F.R. 4849–4855 (1977).

[97] 15 U.S.C. 2076(b)(1) and (e).

(ii) *The remedies available to the CPSC when a hazard is present*

This section will focus on the regulatory action taken by the CPSC, the regulatory alternatives that were available to the agency, and, the regulatory action that should have been taken to limit or eliminate the hazard of Tris-treated children's sleepwear.

What were the regulatory alternatives available to the CPSC to limit or eliminate the hazard of Tris-treated children's sleepwear?

In the case of Tris, the Commission had the power to:[98]

Warn the public about the hazard by labeling the product;

Stop the production and distribution of the product by banning it; and

Remove the product from the homes of consumers by requiring manufacturers to recall, replace, and/or repurchase.

Labeling: *Warning the Public About the Hazard.*—The CPSC did not consider labeling to warn the public about the potential hazard. Provisions for labeling are available under the Federal Hazardous Substances Act (FHSA)[99] and the Consumer Product Safety Act (CPSA).[100]

The following is a discussion of the provisions that should have been considered by the CPSC.

According to section 30(d) of the CPSA, the transferred acts (in this case the FHSA is the transferred act that would be applicable to the regulation of Tris.) shoud be given preference over the application of provisions in the CPSA. That is, the CPSA can be applied as opposed to one of the applicable transferred acts if the CPSC, by rule, finds that it is in the "public interest" to apply the CPSA.[101]

"Public Interest" is set out but not defined in the CPSA. Because "public interest" is not defined in the act, it provides the CPSC with ample flexibility to apply the CPSA instead of the transferred acts. For example, if application of the CPSA would be more effective or or expeditious than one of the transferred acts then it presumably would be within the "public interest" to apply the CPSA.

But, the FHSA, in this case would not have been as effective as the CPSA in providing an expeditious warning and, therefore it would be be in the "public interest" to apply the CPSA. Under the FHSA, labeling as prescribed by section 2(p)[102] is required for any chemical substance that meets the criteria of the definition of "hazardous substance" as enumerated in section 2(f)(A) of the FHSA. But the definition of a "hazardous substance" as contained in the statute does not specifically enumerate carcinogens.[103]

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[98] Sec. 2(b); 55 U.S.C. 2051(b).

[99] 15 U.S.C. 1261 et seq. The FHSA is an act transferred to the jurisdiction of the CPSC as specified by Sec. 30 of the CPSA.

[100] 15 U.S.C. 2056(a) and 2076(e).

[101] 15 U.S.C. 2079(d): "A risk of injury which is associated with a consumer product and which could be eliminated or reduced to a sufficient extent by action under the Federal Hazardous Substances Act, the Poison Prevention Packaging Act of 1970, or Flammable Fabrics Act may be regulated under this Act only if the Commission by rule finds that it is in the public interest to regulate such risk of injury under this Act * * *" Unfortunately, "public interest" is not defined in the act.

[102] 15 U.S.C. 1261(p): According to sec. 2(p) a substance is a "misbranded hazardous substance" if it is not labeled as prescribed by that section. A misbranded hazardous substance is prohibited from introduction into interstate commerce by section 4, 15 U.S.C. 1263. *See also* 15 U.S.C. 1264 and 1265.

[103] "Hazardous substance" is defined in sec. 2(f)(a) of FHSA (15 U.S.C. 1261(f)1(A): "Any substance or mixture of substances which (i) is toxic, (ii) is corrosive (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substance may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children."

A carcinogenic substance would fall within the definition of "hazardous substance" (Section 2(f)(1)(A)) and more specifically, the definition of "toxic" (Section 2(g)).[104] But carcinogens are not specifically set out in the FHSA "toxic" definition, and, the CPSC has to date failed to enact further regulation to supplement the "toxic" definition that would specifically include Tris or other carcinogens within the definition of "toxic" and the definition of "hazardous substance."

The regulations that have been enacted by the CPSC to supplement the "hazardous substance" definition have the effect of narrowing the definition of "toxic" toward those substances with immediately discernible effects and away from substances whose effects are of a more chronic nature such as carcinogens.[105]

When there is uncertainty as to whether a substance comes within the FHSA definition of "hazardous substance," the Commission could clarify that definition by regulation.[106] But, proceedings for such a regulation must be governed by provisions 701 (e), (f), and (g) of the Federal Food, Drug and Cosmetics Act.[107] Proceedings governed by provision 701 (e), (f), and (g) are often two phase, protracted proceedings.[108] [109] And, lengthy proceedings would defeat the purpose of a timely warning.

Alternatively, section 30(d) of the CPSA allows the CPSC to apply the provisions of the CPSA rather than the provisions of the acts transferred to its jurisdiction, when ever the "public interest" would be better served by applying the CPSA. Under CPSA, there are provisions for labeling under sections 7 and 27(e).[110]

Section 7 allows the Commission to set consumer product safety standards to protect the public. Such standards include the power to presiribe labeling.[111] However, the procedural requirements of section 7 make it more suitable for imposing long-term performance requirements. In addition, its lengthy procedural requirement would, like those of the FHSA, defeat the purpose of providing a timely warning to the public for a product that is already in a marketplace and in many of the consumers homes. The procedures necessary for enacting section 7 include not only the administrative requirements of rulemaking but also must include the consideration of an offer to develop a proposed consumer product safety standard.[112]

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[104] 15 U.S.C. 1261(g): "the term 'toxic' shall apply to any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface."

[105] 16 CFR 1500.3(c)(2).

[106] 15 U.S.C. 1262(a).

[107] 21 U.S.C. 371(e) (f) and (g).

[108] Two years ago, Commissioner R. David Pittle testified as to the difficulty of operating under 701(e) procedures:

> Procedures under this section 701(e) have taken as long as 10 years from the formulation of the original proposal to the actual effective date of the regulation.

An important point to be noted in considering procedures that involve protracted proceedings is that an opportunity for hearings does not have to mean a right to a hearing in every case.

Commissioner Pittle further testified to the feasibility of summary judgment rules to—

> Expedite hearings where little factual dispute exists and would avoid the necessity of prolonged proceedings.

"Regulatory Reform—vol. IV, Consumer Product Safety Commission," Hearings Before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 94th Cong., 2d sess., ser. No. 94-83, Jan. 30 and Feb. 19, 1976, at 42 [hereinafter cited as *Regulatory Reform Hearings*].

[109] As later disclosed in the subcommittee report, the CPSC has had the regulatory power to set out detailed guidelines as to when a hearing should or should not be granted. But, the CPSC has failed to promulgate such rules and therefore must provide a hearing in every instance where statutes require "an opportunity for a hearing." The report further notes that other agencies have promulgated summary judgment rules setting forth criteria for the denial of a hearing and such rules have prevailed when challenged in the courts. *Regulatory Reform Report*, supra note 3, at 226–227.

[110] 15 U.S.C. 2056, 2076(e).

[111] 15 U.S.C. 2056 (a)(1): The Commission may by rule, in accordance with this sec. 9, promulgate consumer product safety standards. A consumer product safety standard shall consist of one or more of any of the following types of requirements:

> (A) Requirements as to performance, composition, contents, design, construction, finish, or packaging of a consumer product.
>
> (B) Requirements that a consumer product be marked with or accompanied by clear and adequate warnings or instructions, or requirements respecting the form of warnings or instructions.

Any requirement of such standard shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product. The requirements of such a standard (other than requirements relating to labeling, warnings, or instructions) shall, whenever feasible, be expressed in terms of performance requirements.

Under section 27(e) of the CPSA, there are provisions that allow the Commission to require by rule:

> Notification of such performance and technical data at the time of original purchase to prospective purchasers and to the first purchaser of such products for the purpose other than resale, as it determines necessary to carry out the purposes of this act.

The procedural requirements for implementing the provisions of section 27(e) make it more suitable for providing an expeditious warning than either of the procedural specifications required by section 7 of the CPSA—or provisions of FHSA.[113] [114]

Ban: *Provided with Evidence that the Product was a potential Hazard—the Commission Should consider imposing a Ban on the Product.*—The CPSC relied upon section 2(q)(1)(A) of the FHSA to ban Tris. Section 2(q)(1)(A) of the FHSA is an appropriate provision for banning Tris-treated children's sleepwear because it applies specifically to hazardous substances intended for use by children.[115]

Section 2(q)(1)(A) of the FHSA provides that "hazardous substances which are susceptible to access by children are "banned hazardous substances." Thus, if the CPSC determines that the substance is a hazardous substance and is susceptible to access by children it automatically puts a ban into effect. Upon application of section 2(q)(1)(A), the Commission would have to notify manufacturers and others that it considers Tris-treated children's sleepwear to be a "banned hazardous substance" and that any manufacture, distribution, or sale of it is therefore a violation of the FHSA. In addition, upon application of section 2(q)(1)(A), automatic repurchase specified by section 15 [116] of the FHSA, would be triggered.

The CPSC has made the contention that Tris meets the statutory definition of "hazardous substance" contained in section 2(f)(1)(A) of the FHSA because it is a "toxic" within the meaning section 2(g) of the FHSA. The statute provides that a substance may be determined to be "hazardous substance" because it meets the definition of "hazardous substance" under section 2(f)(1)(A) or because it has been so defined by the CPSC by regulation.

The CPSC encountered difficulty in their application of section 2(q)(1)(A) because the CPSC failed to define by regulation that Tris was a "hazardous substance" under section 2(f)(1)(A). The CPSC could have utilized section 3(a) of the FHSA which provides for a rulemaking determination to avoid uncertainty as to whether the substance (Tris) was a "hazardous substance" as defined by section 2(f)(1)(A).

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[112] 15 U.S.C. 2056, 2058.

[113] 15 U.S.C. 2076(e)

[114] There also are provisions under 15 U.S.C. 2064 for notifying the public of a product defect or a product the Commission when there has been a determination (after affording interested persons an opportunity for that fails to comply with "an applicable consumer product safety rule". Such notification may be ordered by hearing) "that a product distributed in commerce presents a substantial product hazard and that notification is required in order to adequately protect the public from such substantial product hazard * * *".

[115] Specifically, the sec. 2(q)(1)(A) provides: "The term 'banned hazardous substance' means (A) any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted."

[116] 15 U.S.C. 1274.

By not promulgating a regulation according to the procedures required by section 3(a)(2) to resolve their determination that Tris was a "hazardous substance," the CPSC set in motion the automatic remedies (ban, repurchase) even though they could be penalizing manufacturers, distributors and retailers by denying them the opportunity to contest the merits of the Commission's action in a rulemaking proceeding.

As the CPSC should have predicted, those subject to the ban and repurchase raised due process questions.

The court focused on such due process questions in *Spring Mills, Inc.* v. *Consumer Product Safety Commission;* 434 Fed. Supp. 416 (D.S.C. 1977).[117] There, in imposing a permanent injunction on the CPSC, and declaring the ban on Tris was null and void, the Court stated:

> The basis issue is whether plaintiff [Spring Mills] has been denied due process of law because of actions taken by the Consumer Products Safety Commission in declaring TRIS a "banned hazardous substance" within the meaning of 15 U.S.C. § 1261(q)(1)(A) in not conducting a rule-making hearing with proper notice to those affected by the proposed ban and an opportunity for it to appear, present testimony and cross-examine witnesses presented by the Commission and test the weight and sufficiency of the evidence considered by the Commission. This claim denial of due process could result from either an unconstitutional interpretation placed upon the law by CPSC or from a finding that the statute itself is unconstitutional. (at 427)

The Court further concluded:

> The due process requirements of the Constitution do not fly out of the window when the rights of children come in the door. Even a person, who admits committing the most grievous crime against a child, is still entitled to due process of law, and the fact that a child may use a top or an article does not deny due process protection to the retailer, manufacturer or supplier of a component part of such article. *The obvious intent of Congress was that after a proper finding of "hazardous substance," if the top or article was obviously intended for use by children, then the term "banned hazardous substance" could be applied to it and thereby invoke the repurchase provisions of § 1274.*
>
> *To interpret § 1261(q)(1)(A) and § 1262(a)(1) as urged by the defendents would require a finding that Congress had enacted a patently unconstitutional law.* This construction must be avoided by the Court *when* possible. (Emphasis added) at 432.

Both the CPSA and the FHSA have other provisions that could have been employed to ban Tris-treated children's sleepwear.[118] Provisions for a "ban" under either statute have procedural requirements that must be satisfied before a ban can be imposed. The procedures basically include notice and opportunity for a hearing by parties that may be adversely affected.[119]

The statutes also provided an exception to this hearing requirement by inclusion of the "imminent hazard" provisions.[120] [121] Under the

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[117] *Spring Mills*, supra, decision is now on appeal to the U.S. Court of Appeals for the Fourth Circuit.

The Court of Appeals, in denying a stay of the injunction against the Commission pending appeal, held: "The injunction does not preclude the Commission from taking action against any individual manufacturer or seller of the subject article that is alleged to be hazardous seeking the imposition of criminal penalties under 15 U.S.C. sec. 1264, seizure under 15 U.S.C. sec. 1265, or an injunction under 15 U.S.C. sec. 1267."

[118] 15 U.S.C. 1262, 2057. See 15 U.S.C. 1262, 2057, 2058.

[119] 15 U.S.C. 1261(g)(2), 2061.

[120] In addition to expeditious action available under "imminent hazard" provisions, both the FHSA and the CPSA have provisions that give the CPSC power to seek action against individual violators of the acts. Under the FHSA: *See* 15 U.S.C. 1264, 1265, 1267; under the CPSA; 15 U.S.C. 2069, 2070, 2071.

[121] When their 2(q)(1)(A) ban was thwarted in the courts, the CPSC attempted to act against an individual seller of Tris-treated products by directing a seizure (as provided by 15 U.S.C. 1265) of Tris-treated being

FHSA where the Commission has determined that a substance is an "imminent hazard" a ban goes into effect immediately and the procedures for hearing the affected parties are undertaken thereafter.

Application of Imminent Hazard Provisions.—The CPSC could have imposed a ban while proceedings were pending by using its "imminent hazard" powers. The evidence available to the CPSC regarding the adverse effects of Tris allowed for an immediate ban of the substance. Both the CPSA and the FHSA have "imminent hazard" provisions. But, the FHSA provides for an "imminent hazard" ban. Therefore, CPSC should have used section 2(q)(2) of the FHSA to declare Tris an "imminent hazard,"

The court in *Spring Mills*, supra., suggested that section 2(q)(2), be used as an alternative to section 2(q)(1)(A), to provide expeditious remedy against Tris:

> *If the Commission genuinely believed that Tris treated fabrics present such an imminent danger to the public* health that all distribution of the fabrics and garments by others must be suspended, before the rule making procedures mandated by Congress in 15 U.S.C. 1262(a)(1) and (2) can be completed, it had two clear remedies available. First, the Commission could have filed suit for an injunction in the district court and would be entitled to a temporary restraining order or a preliminary injunction upon compliance with Rule 65 as expressly provided by 15 U.S.C. 1267(a). Second, the Commission could have proceeded under 15 U.S.C. 1261(q)(2) by making a finding of "imminent hazard," which finding would then be subject to judicial review.[122] (Emphasis added.)

Pursuant to section 2(q)(2), if the CPSC finds that the substance presents an "imminent hazard," the CPSC may by an order published in the Federal Register deem that the substance is a "banned hazardous substance." [123] Whereupon, a ban of the hazardous substance takes effect immediately and stays in effect pending the outcome of the administrative proceeding.

The Food and Drug Administration (FDA) regulation which defines "imminent hazard" under FHSA remains in effect even though the FHSA has been transferred to the CPSC.[124]

As noted earlier, the CPSC will have to conduct rulemaking proceedings according to the procedures described in sections 701 (e), (f), and (g) of the Food, Drug and Cosmetic Act to determine whether or not a substance is a "hazardous substance," [125] such a proceeding could

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sold by Taxler Hosiery. The court in *U.S.* v. *Articles of Hazardous Substances, etc.* in quashing the warrant of seizure, described the CPSC change in tactics:

> On December 6, 1977, the Commission withdrew its earlier "publications" banning TRIS: In their place the Commission issued a policy statement, reiterating its belief that TRIS products are banned hazardous substances. To support this belief, the Commission simply cited its earlier publications and undisclosed new information. The Commission also stated its intention to file individual enforcement actions to prevent sales of TRIS products. The Commission also stated that in these enforcement actions the Commission could and would not rely on its previously published "interpretations" or on its new "policy statement" to prove any hazards associated with Tris. 42 F.R. 61621–22 (1977).

Articles, supra, quashed the warrant of seizure on the theory that Troxler's constitutional rights were violated.

A single circuit judge for the fourth circuit granted a stay of the order quashing warrant of seizure, and, pending appeal of *Articles* supra. and, consolidating the appeal of *Articles* with the *Spring Mills* supra., appeal.

[122] *Order* C.A. 77–891 (May 1977).

[123] 15 U.S.C. 1261(q)(2).

[124] 21 CFR 2.5 states that:

> * * * [A]n imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat or danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held * * * the occurance of the final anticipated injury is not essential to establish that an "imminent hazard" of such occurrence exist * * * In exercising judgement or whether an "imminent hazard" exists. the (CPSC) will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury.

The CPSC could, modify, terminate, supercede, set aside or repeal this regulation pursuant to 15 U.S.C. 1261–62, 1269, 2079; however, since it has not, the regulation (and therefore the definition) remains in effect according to 15 U.S.C. 2079(e)(2).

[125] See text accompanying notes 5–9 supra.

be combined with section 701 (e), (f), and (g) proceedings required pursuant to declaring that the substance presents an "imminent hazard" under section 2(q)(2).[126] The fact that the proceedings under sections 701 (e), (f), and (g) are protracted proceedings is irrelevant in imposing a ban under the "imminent hazard" provision because the proceedings are after-the-fact and ban will be imposed pending the completion of the proceedings. This, of course, means that the hazard will be checked pending the completion of the proceedings.

The CPSA also has provision for declaring a product an imminent hazard.[127] The CPSA section 12 [128] provides for a spectra of remedies including seizure upon a declaration by a U.S. district court that the product presents an imminent hazard: That it is "a consumer product which presents an imminent hazard and unreasonable risk of death, serious illness or severe personal injury." [129]

The CPSC can file in a federal district court against an "imminently hazardous consumer product" for seizure of such product and/or against a manufacturer, distributor or retailer of such a product.[130] The court in addition to declaring a product an "imminently hazardous consumer product" is empowered to grant such temporary or permanent relief against individual manufacturers, distributors or retailers to protect the public—

> Such relief may include a mandatory order requiring the notification of such risk to purchasers of such products known to the defendant, public notice, the recall, the repair of the replacement of, or refund for, such product.[131]

For the injunctive remedy available under the CPSA to approach the effectiveness of a ban under the FHSA, the CPSC must be able to seize all the products, and/or effect service of process upon all individual manufacturers, distributors or retailers of the products.[132] Therefore, the CPSC would better serve the "public interest" by applying the FHSA "imminent hazard" provisions and impose a ban on the substances it believes present an "imminent hazard." [133]

As a secondary alternative to the imminent hazard provisions, the CPSC could have applied those sections that provide for a ban after an administrative proceeding.

Under the FHSA, sections 2(q)(1) (A) and (B)[134] are available for imposing a non-"imminent hazard" ban. In applying either 2(q)(1) (A) or (B), 701(e) (f) and (g) proceedings are required before a ban can be imposed on Tris-treated children's sleepwear.

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[126] Through sec. 701(e) proceedings required by sec. 2(q)(1)(B), 15 U.S.C. 1261(q)(1)(B) and (3)(a), 15 U.S.C. 1262(a) have been combined previously by the CPSC, they have not combined the sec. 701(e) proceedings when using the FHSA imminent hazard provision. These proceedings have combined successfully by the FDA: 15 U.S.C. 1261(9)(2).

[127] Under the CPSA, "The Commission (CPSC) may file in U.S. district court an action (1) against an imminently hazardous consumer product * * * (2) against any person who manufactures, distributes, or retails of such product, or (3) against both. The district court in which such action is filed shall have jurisdiction to declare such product an imminently hazardous consumer product." Sec. 12; 15 U.S.C. 2061.

In addition to expeditious action available under "imminent hazard" provisions, both the FHSA and the CPSA have provisions that give the CPSC power to seek injunctions against certain violations of the acts. Under the FHSA: *See* sec. 8; 15 U.S.C. 1267. Under the CPSA: *See* sec. 15(q), 22; 15 U.S.C. 2064(g), 2071.

[128] 15 U.S.C. 2061.

[129] 15 U.S.C. 2061(a). The Regulatory Reform Report noted that the CPSC has not adopted any regulation to elaborate this definition of "imminent hazard." It also cited the importance of such regulations for: "(a) guidance to Commission (CPSC) officials in the exercise of their regulatory responsibilities and (b) grounds to support a Commission determination in court. Moreover, if carefully drafted, it need not deprive the Commission of the flexibility necessary to the effective use of this important power." *Regulatory Reform Report*, supra note 3, at 227.

[130] 15 U.S.C. 2061.

[131] 15 U.S.C. 2061(b).

[132] The class rule: F.R. Civ. P. 23, could allow the CPSC to use a method other than personal service on the individual manufacturers, retailers, and distributors.

[133] See text accompanying notes 100 to 102.

[134] As an alternative to sec. 2(q)(1)(A), sec. 2(q)(1)(B) offers broader regulatory coverage because it could affect all wearing apparel that is Tris-treated as opposed to only children's sleepwear under 2(q)(1)(A). But, when a determination is made that Tris is a "banned hazardous substance" under 2(q)(1)(B), there are two issues which require 701 (e), (f), and (g) 21 U.S.C. 371 (e), (f), and (g) proceedings. One, the CPSC will have to make a determination that Tris is a hazardous substance and, two, that Tris is a "banned hazard substance," as defined by 2(q)(1)(B).

Proceedings on these two issues could have been combined into one in the past.

Under section 8 of the CPSA, the CPSC could have imposed a ban with shorter, less cumbersome procedural requirements than under 2(q)(1) (A) and (B) of the FHSA and, therefore, that section should have been considered by the CPSC as the second-best alternative to FHSA 2(q)(2) imminent hazard provisions.

CPSA section 8 [135] provides for a ban of a hazardous product when the Commission finds that the product presents "an unreasonable risk of injury" and that no "feasible consumer product safety standard (provided by sec. 7) would adequately protect the public from the unreasonable risk of injury."

Would a consumer product safety standard for Tris-treated children's sleepwear, "adequately protect the public from the unreasonable risk of injury"? If the Commission attempted to stop the production and distribution of Tris-treated children's sleepwear, a standard would not be adequate because section 7 standards are limited to products manufactured after its effective date while section 8 could ban all existing products as well.[136]

Even if the Commission wanted the action against Tris to only have prospective effect, the Commission may find that a "standard" is not very feasible. A consumer product safety standard which is designd to eliminate all Tris-treated children's sleepwear would be more akin to a "ban" than "standard." [137] In addition, the procedural requirements for acting under section 7 are protracted in comparison with those required for a ban under section 8.[138]

The procedures for enacting a ban under the FHSA and for issuing standards, recall or repurchase under section 7 [139] of the CPSA are more cumbersome than section 8 and therefore will be more lengthy and resource-consuming that section 8 of the CPSA. Section 8 would be recommended as an alternative to the "imminent hazard" provisions of the FHSA for imposing a ban on Tris.

Recall: *Removing the Hazardous Substance from the Households of Consumers.*—When the CPSC determined that Tris-treated sleepwear was a "banned hazardous substance" under section 2(q)(1)(A) of FHSA, the Tris-treated garments were automatically subject to repurchase under section 15 of FHSA. Section 15 provides that "banned hazardous substances" shall be repurchased by the manufacturers, distributors, and retailers. But, enforcement of the ban and repurchase has been enjoined while the legality of CPSC determination under 2(q)(1)(A) is contested. (See text accompanying notes 116 to 118 for a discussion of the CPSC's difficulties of imposing a ban under 2(q)(1)(A).)

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[135] 15 U.S.C. 2057.

[136] Sec. 9(d)(1) of CPSA (15 U.S.C. 2058(d)(1))

[137] Consumer product safety standards are according to sec. 7(a)(1) of the CPSA, to be expressed whenever feasible in terms of performance requirements. (15 U.S.C. 2056(a)(1)).

[138] 15 U.S.C. 1261(q), 2056, 2057, 2058.

[139] Sec. 15 of the CPSA could be considered in their effort to remove a product from the marketplace. (15 U.S.C. 2054).

Sec. 15 provides for remedies against products already in hands of the consumer that do not comply with an applicable consumer product safety rule or have a "product defect which creates a substantial risk of injury to the public." Specifically, the section contains provisions for public notification, repair, replacement, and repurchase of the product. *See* 15 U.S.C. 2064 (f). The Commission may use these remedies only after adjudicated proceedings (before an administrative law judge). (15 U.S.C. 2064(c)(d)) Such proceedings have as a prerequisite service of process on individual manufacturers, distributors and retailers. Or the Commission may, while an adjudicated proceeding is pending, seek a preliminary injunction restraining the distribution of products which the Commission has reason to believe present "a substantial product hazard." 15 U.S.C. 2064(f).

The CPSA also has provisions that would provide for the removal of a "hazardous substance" (or product) from the homes of consumers. The CPSA provisions that would give this type of remedy are sections 12 and 15.[140] Section 12 is not desirable for both substantive and procedural reasons. As stated earlier, procedurally, section 12 (the imminent hazard section) of CPSA requires the CPSC to file an action in a U.S. district court asking the court having jurisdiction to declare the product an "imminently hazardous product" and, this carries with it the requirement of service of process on individual retailers, manufacturers and distributors. On the substantive side, difficulties may arise when the court, which may choose from a broad spectrum of remedies may decide not to include recall among its remedies.

Similarly, section 15 requires an adjudicatory hearing before manufacturers and those in the chain of distribution can be ordered to recall unsafe products. Notice of the proceeding must be given to those who may be subject to the recall order. The CPSC must prove in the adjudicative proceedings that the product has a "product defect" which presents a "substantial risk of injury to the public."

The procedural requirements for application of sections 12 and 15 of CPSA contrast with the repurchase provisions of the FHSA. The FHSA repurchase provisions are triggered automatically when a determination is made that a substance is a "banned hazardous substance" under 2(q)(1)(B).

Since the ban of Tris under 2(q)(1)(A) was not effective, the CPSC should have made a finding that Tris is an imminent hazard under 2(q)(2) of the FHSA and therefore a "banned hazardous substance" as defined by 2(q)(1)(B), thus, triggering the automatic repurchase.

In summary.—When presented with the hazard of Tris-treated children's sleepwear, the CPSC:

1. Could have warned the public about the hazard, but did not.
2. Could have stopped the production and distribution of Tris-treated sleepwear, but failed to impose an effective ban.
3. Could have removed Tris-treated sleepwear from the homes of consumers through a recall, replacement or repurchase, but they failed to effectively impose a ban that would have triggered an automatic repurchase.

(*b*) CPSC failed to investigate the potential hazard posed by Tris properly and in a timely fashion.

In July 1973, an internal proposal by Dr. E. P. Mazzola was presented to the Commission which called for research into the use of flame-retardant chemicals in fabrics; it was turned down.[141] That same year the Commission was informed that one flame-retardant, Tris, was being placed on the NCI bioassay test list because it was suspected of being a carcinogen. However, the Commission took no action that year or the following year to investigate the production or toxicity of Tris.[142]

Interest in the potential toxicological effects of Tris on humans was raised again in the fall of 1975.[143] At that time, the CPSC supplied a sample of Tris to the Environmental Protection Agency for experiments on its potential mutagenicity. These tests, conducted by Dr. Herbert S. Rosenkranz, indicated that Tris was a potent mutagen in bacterial systems and, therefore, was potentially mutagenic and carcinogenic in animals and humans.[144]

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[140] 15 U.S.C. 2061, 2064.

[141] *Hearings*, supra note 12, at 372.

[142] Id. The "History of the Tris Issue" proved to the subcommittee by CPSC indicates that the Commission took no action in 1974 to further explore the potential hazard posed by Tris.

[143] Id.

The Rosenkranz test results were described by the Commission staff as a "red flag." [145] Nevertheless, the Bureau of Biomedical Sciences (BBS) did not suggest that the Commission conduct additional tests on Tris nor did it request that the Commission require manufacturers of Tris to supply it with toxicological data.

The Commission's failure to take swift action to investigate properly the potential hazard posed by Tris may be explained by several factors.

First, according to a study by the National Academy of Sciences (NAS), the Bureau of Biomedical Sciences did not, until recently, consider the existence of potential chronic hazards in consumer products an worthy of emphasis.[146]

The NAS Committee to Review the Operation of the Bureau of Biomedical Sciences of CPSC declared:

> While everyone is deeply concerned about the acute effects from exposure to potentially hazardous material, *very little attention has been given to consumer products that may produce illness and death from chronic exposure to chemicals.*[147] [Emphasis added.]

The Committee declared further that:

> The surveillance systems now in use are not effective mechanisms for collecting such data (data on potential chronic hazards).[148]

Without direction from the Commission to look more carefully at potential chronic hazards posed by consumer products, the staff has concentrated its research effort almost exclusively on substances in consumer products that might cause acute effects.[149] Scientists in the Bureau have been interested almost entirely in immediate toxic effects occurring when the product is swallowed, inhaled or absorbed through the skin. Substances like Tris were examined in-depth only if they were "strong" skin sensitizers.[150]

Second, the Bureau of Biomedical Sciences has neither the expertise nor the facilities to evaluate properly potential chronic hazards. The National Academy of Science Committee report states that:

> The Committee (NAS Review Committee) believes that the staff resources and skill mix are not adequate to meet the agency's acute hazards. *They are unquestionably inadequate to address chronic hazards.*[151] [Emphasis added.]

The Committee went on to state that if the Commission decides to consider chronic hazards in its regulatory research program "* * * additional skills will be needed in such areas as experimental oncology, teratoloty, mutagenesis, biochemistry, and pharmacokinetics." [152]

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[144] Letter from Glenn E. Schweitzer, Director, Office of Toxic Substances, Environmental Protection Agency, to Mr. Stanley R. Parent, Exective Director, CPSC, Oct. 29, 1975.

[145] The results of these tests were described as "red flags" in a memornadum from R. E. Osterberg to R. M. Hehir, Bureau of Biomedical Sciences, Oct. 31, 1975.

[146] *A Review of the Role of Health Sciences in the Consumer Product Safety Commission*, report by the Committee on Toxicology Assembly of Life Sciences, National Research Council, National Academy of Sciences, (hereinafter cited as *NAS Report*) at 6.

[147] Id.

[148] Id.

[149] Id. at 14.

[150] Id. at 13.

[151] Id. at 14.

[152] Id.

Furthermore, the NAS committee concluded that CPSC has totally inadequate testing facilities. The NAS committee stated:

> The animal feeding facilities are small and totally inadequate to meet today's needs for conducting toxicological investigations. The laboratories are * * * so cramped as to preclude anything other than token studies of an elementary nature." [153]

A review of the laboratory facilities by the Subcommittee staff tended to support this finding.[154]

Third, although almost all the information on Tris was supplied by sources outside the Commission, the Director of the Commission's BBS considered the information provided insufficient reason to suggest that the Commission fund accelerated research on Tris until early 1977. Although the information provided the Commission did not specifically demonstrate adverse human effects, it did suggest that Tris might pose a major hazard to humans, especially children. The Environmental Protection Agency, the Food and Drug Administration, Dr. Ames, Dr. Harris and others, tried to stimulate CPCS to take further action on Tris. Nonetheless, Dr. Hehir and others found the information provided "too equivocal" to support regulatory action.[155]

Until July 1976, the Commission allocated no funds to conduct its own research on the toxicology of Tris.[156] These tests, when finally undertaken, were not conducted with great urgency and were not completed until March 1977.[157]

Furthermore the Commission did not begin tests until January 1977 to determine:

(1) How much Tris was available for absorption or ingestion by children; and

(2) Whether Tris in treated garments could be absorbed through the skin and at what rate.[158]

Numerous studies including: 90 day feeding studies; studies designed to determine the amount of Tris which may be absorbed through the skin of animals; and, studies designed to determine how much Tris was actually available for ingesting and/or absorption, could have resolved many questions about Tris' safety.[159] Information could have been available at an earlier date making it possible for the Commission to assess, in an informed manner, the potential danger posed by Tris, well before April 1977.

(*c*) CPSC failed to take timely action once information was received indicating that Tris was a potential hazard.

After waiting passively for the scientific community to bring information to it on Tris, the Commission then failed to take appropriate and timely action once information was provided that would have justified regulatory action at a date considerably earlier than the Commission's action. CPSC could have, at least, informed consumers that Tris-treated sleepwear presented some risk. The Commission offered several explanations for its failure to take more speedy action on Tris.

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[153] Id. at 9.

[154] The subcommittee staff reviewed the CPSC laboratory facilities in Washington on Dec. 21, 1977.

[155] Internal memorandum from Dr. Osterberg to Dr. Hehir, Bureau of Biological Sciences, CPSC, Oct. 31, 1975.

[156] Memorandum prepared for the subcommittee from the Bureau of Biomedical Sciences, March 1978, regarding CPSC scientific research of Tris.

[157] Several 13 week subchronic toxicity studies were funded by the Commission in July 1976.

[158] Id.

[159] Id.

(i) *"Unequivocal Proof" of Hazard*

One argument presented by the Commission to defend its slow action on Tris concerns the level of proof it must have before taking action. CPSC was apparently searching for "unequivocal" evidence of a human health hazard. A review of the Bureau of Biomedical Sciences August 2, 1977, memorandum is illustrative.[160]

In a memorandum from Dr. Robert Hehir to Albert Dimcoff concerning the Bureau of Biomedical Sciences (BBS) review of the EDF petition, Dr. Hehir stated several times that the Bureau needed "unequivocal" evidence of the potential hazard posed by Tris. Dr. Hehir concluded his memorandum by stating:

> Although present data indicate some correlation between mutagenicity and carcinogenicity of a chemical, an *unequivocal* relationship has not yet been established.[161]

Chairman Moss expressed the subcommittee's concern about the Commission's perception of the level of proof needed before action could be taken, when he stated:

> Mr. Moss. I think that something is being overlooked here, for all practical purposes, the Commission has adopted this standard. It is set forth in a variety of memorandums I have been reviewing here. It is repeated again in the memorandum from Dr. Hehir on July 21. It is repeated on several instances in the information that the Chairman, Mr. Byington, has prepared in response to questions from the Subcommittee on Commerce, Consumer, and Monetary Affairs in the other body.
>
> You state you must have unequivocal evidence. That is used here repeatedly. Nowhere in this act—nowhere—nor in the study by the Elkind Commission which led to the act being passed by the Congress is there the inference that that test should be applied.
>
> Yet, that is the test that is being applied. I am telling you gentlemen you better change your perception of the level of proof involved or we will change it for you. Your contention that the evidence must be unequivocal is clearly going way, way beyond what this Congress intended.
>
> I do not think anyone can speak more clearly to that than the members of this committee, which reported the legislation on this side and the members of the comparable committee on the other side.[162]

Nowhere in the act does it state that the Commission must have "unequivocal proof" of a hazard. Rarely, if ever, is such proof possible. CPSC or at least certain staff members appear to have invented a standard and in the process misinterpreted the intent of Congress.

The subcommittee believes the Commission should have taken "regulatory action that is precautionary" as Commissioner Pittle appropriately stated it could have done.[163] CPSC did not have to prove "unequivocally" that there was a hazard.

(ii) *Misleading Industry Statements*

A review of the information on Tris in the Commission's possession in August 1976 indicates that the major group claiming that Tris was safe was its prime manufacturer: Michigan Chemical Co. However, in July 1978 Michigan Chemical Co.'s assertion that Tris was safe was termed "scientifically unmerited" and of questionable "objectivity" by one member of BBS.[164] The Commission did not make this important evaluation of Michigan Chemical Co.'s assertion public.

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[160] Memorandum from Robert M. Hehir, Director, Bureau of Biomedical Sciences to Albert S. Dimcoff, Associate Executive Director for Regulatory Development, Subject; Status Report of BBS Activity on Tris Aug. 2, 1976.

[161] Id.

[162] *Hearings*, supra note 12, at 431.

[163] Id. at 428.

[164] Note 61, supra.

The Commission's inaction left a vacuum in the public's perception of the potential hazard posed by Tris. Organizations outside the Government, including public interest groups and chemical manufacturers not charged with regulating or objectively evaluating Tris, were left to answer consumer questions about the safety of Tris.

The subcommittee's investigation indicates that the Commission, through inaction, allowed the information void to be filled by misinformation provided by the Michigan Chemical Co. There was "staff consensus" that the assertions made by the Michigan Chemical Co. were unfounded. In the following colloquy, Commissioner Kushner was asked why the Commission did not at least publish the staff's critique of the Michigan Chemical Co.'s memorandum on Tris.

> Mr. LUKEN. Well, what if I were to tell you that this memo along with a covering letter from the Michigan Chemical Corp. was sent to the apparel manufacturers of this country—I have a copy of it here—lulling them into a false sense of security with reference to the Tris operation.
>
> This is the Michigan Chemical Corp. memo to the Commissioners. There was, in effect, publication of this memo which comes to the conclusion that—with reference to the EDF petition—there is no harm, no problem.
>
> Mr. KUSHNER. I am unable to answer the question as the whether or not members of our staff might not have communicated this information to the industry or whether or not members of our staff believed that, principally because of the opennesss policy of the Commission, that this information was generally available.
>
> Mr. LUKEN. Was the information also generally available on item No. 16 to Robert Hehir from Dorothy Canter, which raises alarms about the interpretation? That was not available to the manufacturers; was it?
>
> Mr. KUSHNER. I would imagine that that memo would have been as easily available as any of the other memos in the Commission that have dealt with this subject.
>
> Mr. LUKEN. Except that the Michigan Chemical Corp., according to your records, took pain to send it to the manufacturer. The Commission did not.
>
> So, there was publication of the exculpatory memorandum and not of the one that raised the red flag.[165]

Since the Michigan Chemical Co. memorandum provided to the Commission was sent to all its Tris customers,[166] and others, the subcommittee believes that the Commission should have questioned the evidence presented by Michigan Chemical Co. in a public forum. If the Commission had simply stated that it found the Michigan Chemical Co. assertions to be unfounded, Tris might have been removed from the marketplace at a much earlier date. This information may have persuaded some textile mills and garment manufacturers to change to other chemical treatments or fabrics as early as the summer of 1976. This would have greatly reduced the number of Tris-treated garments available for the spring 1977 clothing line.[167]

(*iii*) *Inadequate Management*

Chairman Byington suggested that the Commissioners may not have reviewed all the scientific evidence on Tris because it was in a state of disarray.

> Mr. GORE. I am informed, if I can short-circuit this process, that the Commission did not seek out information from the industry until June of 1976, some 8 or 9 months later.
>
> If you had written regulations on what these standards should be, that would assist you in trying to make these determinations.

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[165] *Hearings*, supra note 12, at 433.

[166] Id. at 239–240.

[167] Id. at 297.

In the fall of 1976, you were presented with another series of tests which are much more predictive of cancer than the Ames test. These are the insect studies.

An industry representative testified here on Friday from Mobil Corporation that they would definitely remove a product if the results of that test showed up positive.

Your staff memoranda showed conclusively that the staff of the Commission was very concerned about this information in the fall of 1976, yet it took another 6 months.

Is the alleged disorganization within the Commission the cause of this delay?

Mr. BYINGTON. My Gore, I think not only the alleged but the actual disorganization within the Commission played a part.[168]

Not only was the Commission disorganized, but it also failed to direct its staff to develop, by a date certain, a consensus on the toxicity of Tris in children's sleepwear.

Mr. LUKEN. Do you believe that the consumer is entitled to notice of the red flag with reference to possible cancer-causing qualities when you have been so advised of a red flag?

Mr. KUSHNER. I think that before I were to urge the Commission to make a public announcement about something, I would expect to get a consensus decision from the Commission's professional staff that such an action was warranted.

Mr. LUKEN. Is that what you did?

Mr. KUSHNER. I did not take steps myself to see whether or not such a consensus could be developed.[169]

As the testimony by Commissioner Kushner points out, however, the Commission never directed the staff to come up with a "consensus" on what should be done about Tris by a certain date, and although the Commission was privy to all the staff memos including the memos by Dr. McLaughlin[170] and Dr. Wyer,[171] it did not exercise its responsibility to take direct action based on the facts before it with or without a staff "consensus".

(iv) *Data Available on the Potential Hazard*

Despite the CPSC's assertions to the contrary, the subcommittee believes that by November 1976 the Commission had enough information to take action to warn consumers about the potential dangers of Tris-treated garments. In December 1976, for example, the Commission had in its possession:

1. Results of the Rosenkranz tests indicating that Tris was a potent mutagen in the Ames test.[172]
2. Test results confirming Rozenkranz's findings.[173]
3. EDF petition alleging that:
    (*a*) Tris was highly toxic to fish at 1 part per million;[174]
    (*b*) Tris was stored in fish tissue;[175]
    (*c*) Tris was an anticolinesterase inhibitor;[176]
    (*d*) High levels of Tris (as high as 70,000 parts per million) were found on the surface of Tris-treated garments;[177] and
    (*e*) Significant amounts of Tris could be ingested through mouthing.[178]

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[168] Id. at 428.

[169] *Hearings*, supra note 12, at 432.

[170] Note 67, supra at 1.

[171] Note 73, supra at 1.

[172] *Hearings*, supra note 12, at 427.

[173] Id. at 482.

[174] The March 1976, EDF petition contained a study by W.H. Gutehmann and P. J. Lisk entitled "Flame Retardant Release from Fabrics During Laudering and Their Toxicity to Fish." This article contains this conclusion. *Hearings*, supra note 12, at 247-250.

[175] Id.

[176] Id.

[177] Note 55, supra.

[178] Id.

4. Test results indicating that:

(*a*) Tris contained a contaminant DBCP which was a known carcinogen, mutagen, and was suspected of causing sterility;[179]

(*b*) Tris could "cause reparable breaks in DNA strands of human cells grown in culture;" [180]

(*c*) Tris could cause "unscheduled DNA synthesis in human cells in tissue cultures;" [181] and

(*d*) Tris could "induce heritable mutations (sex-linked recessive lethals) in *Drosophila melanogaster.*" [182]

Faced with substantial scientific evidence questioning the safety of Tris in children's sleepwear and considering the population exposed—approximately 60 million children—(some who may have worn the treated sleepwear almost 24 hours a day), the prudent course of action for CPSC would have been to at least warn consumers that Tris-treated sleepwear might pose a hazard.[183]

(*v.*) *General Conclusion*

The Subcommittee concludes that the Commission did not (1) take appropriate and timely action on the information provided, (2) provide consumers, on a timely basis, with information to evaluate the potential hazard posed by Tris, (3) did not properly exercise its responsibility to conduct research into preventive measures designed to keep toxic chemicals out of children's sleepwear.

(*d*) CPSC did not take the most effective statutory action available to ban Tris-treated garments from the market.

The CPSC Should Have Used Better Judgment in Choosing from the Remedies Available for Dealing with a Hazard.—As discussed in section (a), the CPSC attempted to ban Tris-treated children's sleepwear by publishing in the Federal Register their interpretation that Tris was to be defined as a "hazardous substance" (42 Fed. Reg. 18850 1977)). The CPSC was later enjoined by a U.S. district court for the District of South Carolina from enforcing the interpretation banning Tris.

The subcommittee believes that the CPSC should have made a determination under 2(q)(2) of the FHSA that Tris presented an "imminent hazard to public health." That determination would have stopped the production and distribution of Tris while proceedings were pending. It would also have triggered the automatic repurchase provisions of the FHSA.

In reflecting upon his action in April 1977 to use 2(q)(1)(A) of the FHSA, Commissioner Kushner declared, in October 1977, that Tris should have been declared an imminent hazard—[184]

> Mr. KUSHNER. I think if we had to do it over now, I would vote now to exercise the imminent hazard provisions under Section 2(q)(1)(B) of the Federal Hazardous Substances Act.
>
> Mr. MAGUIRE. Good. Why not reopen the matter in the Commission? You are the swing vote.
>
> Mr. KUSHNER. We made a decision to pursue the Tris matter through litigation in an effort to try to uphold the position that the Commission originally took——
>
> Mr. MAGUIRE. Continues to.
>
> Mr. KUSHNER. ——with respect to a ban under 2(q)(1)(A). I am saying that if I had it to do over again, I think I would have gone imminent hazard under 2(q)(1)(B). I thought we could get the same from section 2(q)(1)(A).

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[179] Note 65, supra.

[180] Id.

[181] Id.

[182] Id.

[183] The CPSC estimated that approximately 60 million children might have been exposed to Tris-treated sleepwear. *Hearing*, supra note 12, at 58.

[184] *Oversight Hearings*, supra note 13, at 469.

The subcommittee is perplexed by the CSPC's continued refusal to utilize its imminent hazard powers. As the subcommittee pointed out in its 1976 Report:

> The Commission's various imminent hazard authorities, though not to be used lightly, should be used with greater frequency than they have been to date.[185]

In summary, CPSC actions used substantial resources without protecting the public from a hazardous stubstance.

(*e*) CPSC failed to issue instructions to consumers which would protect them to the maximum extent feasible from the potential adverse effects of Tris in already washed, Tris-treated garments.

In April 1977, the Consumer Product Safety Commission informed consumers that once Tris-treated sleepwear had been laundered 3 times it no longer posed a significant carcinogenic risk to the wearer.[186] This statement has since been contradicted by much scientific evidence. Disagreement over the CPSC's conclusion occurs on two issues: (1) the effectiveness of laundering in removing "surface" Tris, to which the skin is exposed; and (2) the danger posed by migration of Tris, between washings, from within fibers to the garment surface.

The subcommittee's May 1977 hearings revealed that, in the opinion of many scientists, three washings do not sufficiently reduce the carcinogenic and mutagenic health risk posed by Tris in sleepwear.

Dr. Bruce Ames pointed out that legal standards required children's sleepware to remain flameproof after 50 washings. In order to meet this standard, many textile manufacturers chose Tris because it does not wash out easily, that is, its solubility in water is fairly low.[187] Although surface Tris washes out more easily than Tris bonded in the garment's fibers, Drs. Ames and N. Kim Hooper explained in a March 21, 1977, letter to the CPSC, that the amount of surface Tris removed with each washing is limited by the low solubility of Tris in water.[188] Ames and Hooper estimated that the proportion of surface Tris removed with each washing ranged from 20 percent to 50 percent, depending on the concentration of Tris in the garment. After five washings, the amount of original surface Tris remaining ranged from 18 percent to 34 percent.[189]

When asked to evaluate the safety of washed, Tris-treated sleepwear, Mr. Rauch of the Environmental Defense Fund and Drs. Ames, Harris, and Kay, all expressed the belief that Tris-treated fabrics still posed a significant health risk after three washings.[190] Dr. Kay stated that Tris-treated garments were hazardous "even after 50 washings," and added that after 40 washings, body heat brings Tris from inside fibers to the surface.[191] Dr. Harris stated "I would as a parent not allow my children to wear sleepwear, I do not care how many times it has been washed, if treated with Tris."[192]

There is conclusive evidence that, between washings, Tris diffuses from within garment fibers to the fabric surface, and therefore is available for human skin absorption. Diffusion is an essential factor in determining the total cancer threat the garment poses to the wearer.[193]

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[185] *Regulatory Reform Report*, supra note 3, at 241.

[186] "Commission Votes to Ban Children's Sleepwear Containing Tris," Consumer Product Safety Commission Press Release, Apr. 7, 1977.

[187] *Hearings*, supra note 12, at 83.

[188] Id. at 47.

[189] Id.

[190] Id. at 84.

[191] Id.

[192] Id. at 72.

MCC representatives claimed that five washings would make Tris sleepwear safe. They dismissed the dangers of Tris diffusion as insignificant. However, they did not present any experimental evidence to support their position.

The Consumer Product Safety Commission relied on industry estimates to a great extent in making its own determination about the risk posed by already washed Tris-treated garments. Congressman Gore expressed the subcommittee's concern about the Commission's decision when he stated:

> Your legislative mandate is to protect consumers of these products against potential hazards.
>
> It seems clear to me that you came down on the conservative side of taking the lowest number of washings available.
>
> On one extreme you had three washings proposed. On another extreme you had 50. The absolute other extreme is that no amount of washings can remove it. Yet you chose the lowest possible figure.[194]

The Commission also seems to have dismissed the potential risk posed by the Tris stored, inside garment fibers, which may continue to pose a cancer threat after many washings. Recent studies provide additional evidence that laundered Tris-treated sleepwear exposes children to significant quantities of Tris.

Experiments performed by Drs. Ames and Blum of University of California at Berkeley, and by Dr. Evan Horning of Houston, found metabolized Tris in children's urine—months after the sale of Tris-treated fabrics was banned. Even children who wore old sleepwear, which had been washed many times more than the three launderings recommended by the CPSC, showed traces of metabolized Tris in their urine. Therefore, these children had absorbed Tris through their skin. Other experiments in this study also confirmed that Tris is absorbed through the skin from new Tris-treated sleepwear.[195]

The subcommittee does not believe that there is sufficient evidence to conclude that Tris-treated garments can be rendered safe by three washings. Experiments indicate that laundered fabrics containing Tris may continue to expose their wearers to significant levels of Tris absorption after numerous washings. In light of this evidence—and the fact that CPSC's decision affects the health of millions of children—we believe CPSC did not issue a sufficient warning about the potential health hazard posed by already washed Tris-treated sleepwear.

The Subcommittee recommends that the Commission withdraw its public pronouncement that after three washings Tris-treated garments are safe. The subcommittee further recommends the Commission issue a new warning to consumers about the potential hazard posed by washed, Tris-treated garments.

2. CHRONIC HAZARDS POLICY

(*a*) The CPSC has a legislative mandate to protect the public against chronic hazards.

The Consumer Product Safety Act directs the Commission:

(1) To protect the public against unreasonable risks of injury associated with consumer products;

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[193] Id. at 47.

[194] Id. at 413.

[195] Blum, Gold, Kenyon, Ames, Horning, *et al.*, "Tris-BP Flame Retardant Is Absorbed From Sleepwear: Children's Urine Contains Its Mutagenic Metabolite, Dibromopropanol," Revised Edition, June 9, 1978, Unpublished at this time.

(2) To assist consumers in evaluating the comparative safety of consumer products;

(3) To develop uniform safety standards for consumer products and to minimize conflicting State and local regulations; and

(4) To promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries. (15 U.S.C. 2051(b)

To carry out its legislative mandate, the CPSC has statutory authority to establish a chronic hazards policy. As part of that policy, the CPSC should have been taking ongoing action to monitor and control postatial hazards.

The CPSC can utilize a number of statutory provisions to monitor products that have the potential for causing harm. The CPSC has available under the CPSA power to obtain performance and technical data from manufacturers and conduct (or contracted for) research on any consumer product.

As the subcommittee recommended in the 1976 Report on Federal Regulation and Regulatory Reform:

> First, the Commission itself could devise and conduct testing programs of specific products. There can be no doubt that the Commission has authority to do such testing. It is empowered by Section 5 to (1) Conduct research, studies, and investigations on the safety of consumer products and on improving the safety of such products; [and to] (2) list consumer products and develop product safety test methods and testing devices * * *.
>
> That Congress contemplated that this power encompassed authority to test specific market products is made clear by Section 27(f), which authorizes the Commission to purchase "any consumer product." The Commission could, of course, publish the results of the testing under section 6.
>
> Second, under Section 27(e) the Commission could require manufacturers to conduct the testing and themselves publish the results. Although this power has never been used, it has vast potential. In some instances, it may offer a much less costly and less burdensome alternative to standard setting.[196]

The Report cited another provision that can be used to monitor consumer products: section 13 of the CPSA.[197] Under section 13, the CPSC has the power to promulgate rules requiring manufacturers of new consumer products to furnish notice and a description of the product to the CPSC prior to its distribution in commerce.

The various statutory provisions when used in concert with one another, can provide the CPSC with the knowledge of potential hazards. Such knowledge is necessary if the CPSC is to provide protection for the consumer.

Another aspect of a chronic hazards policy is to establish regulations that further define the CPSC's statutory authority. The CPSC can promulgate regulations that specifically include suspect carcinogens within the FHSA definition of "toxic." The CPSC could have been able to better manage the Tris hazard with a "toxic" definition that includes potential carcinogens.

The CPSC could further define its statutory authority by promulgating rules for summary judgment. By not yet promulgating summary judgment rules, the CPSC has failed to act on another recommendation of the Subcommittee Report. The importance of summary judgment rules becomes apparent when the CPSA is confronted with the requirement of holding lengthy hearing before they can complete regulatory action. Summary judgment rules would expedite hearings where little factual dispute exists and would avoid the necessity of prolonged hearings.

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[196] *Regulatory Reform Report*, supra note 3, at 224-226.

[197] Id. at 224.

The Report stated:

> A number of statutes under which the Commission operates require that parties affected be given an opportunity for a hearing in connection with any contemplated agency regulation or action. Some agencies operating under similar statutes have promulgated rules setting out detailed guidelines as to when a hearing should be granted. The Commission has not. . . .
>
> Congress no more intended "opportunity for a hearing" to mean "right to a hearing" in the Consumer Product Safety Act than it did in the Federal Food, Drug, and Cosmetic Act. The promulgation of summary judgment rules under the CPSA is therefore wholly within the Commission's power. Similarly, the Commission has power to issue summary judgment rules under section 2(q)(1)(B) of the Federal Hazardous Substances Act, as it apparently recognizes.[198]

(*b*) A chronic hazards policy is essential to Commission efforts to regulate hazards like Tris.

The Tris situation demonstrates that the members of the Commission, and the Commission staff, were confused about how and when action could be taken to protect the public from exposure to potentially dangerous chronic hazards in consumer products. Debate on when the Commission could have and should have taken action on Tris indicates that the level of proof needed by the Commission before action may be taken has been left almost entirely to the judgment of each individual Commissioner.

In the Tris case, no guidelines existed for defining a hazard. Hence, the Commission was reluctant to take even interim action to warn consumers about the potential danger posed by Tris.

When asked why the Commission did not take interim action on Tris based on short term mutangenicity test results, Chairman Byington answered that part of the problem was the Commission's failure to have in place a policy defining appropriate action for chronic hazards. He stated, "One of the things all of us (Commissioners) agree on is that we need an internal chronic hazards policy." [199] Commissioner Franklin clearly outlined the issue when she stated:

> In terms of CPSC at this point. I believe the key to better regulation lies in development of a chronic hazards policy tailored to our particular concerns and laws. The policy is critical, and we must act in haste but not in panic. We must recognize that public concern in this area is not going to fade, and neither is our statutory and moral obligation to do something about the problems without unnecessarily burdening industry or detracting our attention from other safety issues. Such a policy must proceed from two fundamental truths—that many of the hazards are complex but controllable and that there are degrees of risk and, therefore, degrees of safety. What it is we must deal with—aggressively an appropriately—are, as our law provides, the unreasonable risks products may pose.[200]

At the subcommittee's May 1977 hearings, the Environmental Defense Fund outlined regulatory difficulties created by the Commission's failure to develop a chronic hazards policy. EDF stated:

> We believe that both of these cases have demonstrated the need for the CPSC to adopt a regulatory policy for dealing with carcinogens in consumer products. For example, although the Commission concedes that both the Federal Hazardous Substances Act and the Consumer Product Safety Act, the Commission's two major sources of statutory authority, do and were intended to reach carcinogens, the Commission has never develop a policy for determining when a carcinogen should be regulated under those two acts. The Commission has regulations defining

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[198] Id. at 226.

[199] *Hearings*, supra note 12, at 418.

[200] Id. at 383.

> the term "toxic substance," one of the sub-categories of substances which are included in the definition of "hazardous substances" under § 2 of the FHSA. However, these regulations do you extend to evidence regarding carcinogenicity. They deal only with the response of animals to extremely toxic materials capable of causing virtually immediate death.
>
> As a result of this oversight, the Agency has no firm guidelines as to what degree of evidence is required before a suspect carcinogen can be considered a "hazardous substance" under § 2 of the FHSA.
>
> Even more important, the Commission has failed to develop regulations or guidelines to assist both its own staff and the public in determining when an imminent hazard to health is presented by a carcinogen or other hazardous substance. Because the Commission has failed to address these questions, the pace of its regulatory activities has been extremely slow. Each case has been dealt with on virtually an *ah hoc* basis. Issues which are common to many cases must be reexamined each time a new threat is presented. The problems created by this lack of a cancer policy are well illustrated in the Tris case.[201]

The Commission's failure to develop a chronic hazards policy until May 1978, has not only led to confusion concerning what regulatory action should be taken but has also left the staff without guidance on what emphasis should be placed on monitoring consumer products for potential chronic hazards.

Moreover, the subcommittee finds that the Commission has not placed proper emphasis on the study of chronic hazards. In a report entitled "A Review of the Role of Health Sciences in the Consumer Product Safety Commission," a National Academy of Sciences panel outlined the need for a greater Commission emphasis on chronic hazards research; the report stated:

> It is the opinion of the committee that the CPSC should concern itself with chronic as well as acute injury. Although the Bureau of Biomedical Sciences, now called Health Sciences, *focused its attention almost entirely on acute injury*, the section of the Act referred to above indicates to the committee that the *CPSC should be equally responsive to problems associated with injury from chronic exposure to potentially hazardous substances*. Real or potential injury can occur which differs only in terms of subtlety and time. A product which produces immediate anoxia or one that produces pulmonary fibrosis five years hence, falls within the spirit and intent of the Act. Both are subject to prevention or regulation. The time required for a substance to exert its impact should have no influence on decisionmaking in the CPSC except to highlight the Commission's role in defining incubation periods and preventing the ultimate injury. (Emphasis added.) [202]

The subcommittee concludes that the Commission must establish a complete chronic hazards policy. It cannot continue to act on an ad hoc basis. Although the Commission's actions to date have focused on defining a policy for potentially carcinogenic substances in consumer products, the Subcommittee believes the Commission should be working toward the development of a policy on other important chronic hazards such as mutagens, teratogens and neurotoxins as well. We also believe that this policy should be revised on a periodic basis, perhaps every two years, to assure that it reflects the latest scientific methods and knowledge on chronic hazards risk detection and evaluation.

(*c*) CPSC has moved too slowly to establish a chronic hazards policy.

At the subcommittee's May 16, 1977, hearings on Tris, CPSC Chairman S. John Byington declared:

> * * * This (chronic hazards policy) was an item that was determined to be of very high priority by the Commission some time ago. The entire proposal on the part of the staff * * * will be to the Commission in the month of June.[203] (1977)

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[201] Id. at 58.

[202] *NAS Report*, supra note 146, at 13.

[203] *Hearings*, supra note 12, at 393.

The staff "proposal" was presented to the Commission on June 17, 1977. An examination of this staff presentation indicates that it was not a "proposal" for a chronic hazard policy but a laundry list of issues related to the chronic hazard issue. The staff document, which is entitled "Chronic Hazards Issue Paper" was, according to its authors, designed:

> (1) To obtain such immediate policy direction as the Commission may be prepared to provide on any of the issues;
>
> (2) To identify issues about which the Commission wants further information; and
>
> (3) To elicit the sense of the Commission and an agenda for further staff effort.

Soon after the Commission received the "Chronic Hazards Issue Paper" it also received another publication concerning its regulation of toxic substances in consumer products: A paper by the National Academy of Sciences National Research Council Committee on Toxicology entitled "Principles and Procedures for Evaluating the Toxicity of Household Substances." The purpose of this report was to update a 1964 report prepared to assist the Food and Drug Administration in fulfilling what were then its responsibilities under the Federal Hazardous Substances Act.[204]

In addition to the two reports mentioned above, the Commission also received the EDF's proposal for a chronic hazards policy,[205] the EPA's carcinogen policy,[206] and the Occupational Safety and Health Administration's proposed cancer policy.[207]

Today, some 17 months after the Commission was petitioned by EDF to develop a chronic hazards policy, it has only published an interim carcinogen policy for public comment. Although the subcommittee recognizes the difficulty inherent in developing a policy of this nature, we find it difficult to believe that the development of this policy has been a "very high priority" for the Commission.

Although the Subcommittee believes CPSC has taken a major step toward improving its regulation of chronic hazards through publication of this policy, we do not believe that the Commission's effort to date has been sufficient.

(*d*) CPSC can contribute to public protection by regulation of chronic hazards.

At the joint oversight hearing on October 3, 1977, S. John Byington, Chairman of the CPSC, stated "* * * To suggest that with our (Commission's) resources we are doing anything other than fly-specking in the chronic hazard area would be facetious." [208]

Mr. Byington's remarks seem to suggest that the Commission believes it has a very small role to play in eliminating chronic hazards or does not have the resources to deal with the problem. We believe only the latter may be true.

The subcommittee believes that in recent years it has become evident that the elimination of chemicals in consumer products posing potential chronic hazards is most important. As pointed out in chapter V, we now know that a majority of cancer may be caused by environmental factors. We also know that many carcinogenic, mutagenic, teratogenic, and neurotoxic compounds are now produced in large quantity;[209] and, that some of these potentially dangerous substances find their way into consumer products.[210] Since the Consumer Product Safety Commission is the only agency empowered to regulate the safety of consumer products, the public must rely on CPSC to vigorously monitor the use of potentially dangerous chemicals in consumer products and carry on research to determine whether levels of potentially dangerous chemicals in these products do indeed pose a health hazard.[211]

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[204] *NAS Report*, supra note 146 at 1.

[205] "Chronic Hazards Issue Paper," CPSC, June 17, 1977.

[206] Id.

[207] Id.

[208] *Oversight Hearings*, supra note 13 ,at 361.

The discovery of the potential hazard posed by Tris in children's sleepwear demonstrates the important role and responsibility of the Commission in the elimination of chronic hazards.

Furthermore, immediate steps can be taken with the Commission's current resources to improve its regulation of chronic hazards. In this regard, the subcommittee believes the Commission should:

(1) Develop "a surveillance program on potentially hazardous consumer products to support compliance action" as suggested by the National Academy of Sciences.

(2) Develop internal staff capability to evaluate potential chronic hazards posed by consumer products.

(3) Request that Congress and Office of Management and Budget provide sufficient resources.

The subcommittee also supports the activities of the Interagency Regulatory Liaison Group including CPSC, EPA, FDA, and OSHA, which has been established to assist agencies in carrying out their responsibilities to protect against chronic hazards.

We believe that this group may provide an appropriate forum for discussion of the development of chronic hazard policies for mutagenic substances, teratogenic substances and neurotoxic substances. We encourage CPSC to continue to take an active part in the Interagency effort but we do not believe that this group can assume the responsibilities of any participating agency. The group can and should be utilized to improve regulation and make it possible for proper chronic hazard regulatory decisions to be made more quickly and efficiently. However, it should not be a reason for CPSC's failure to establish its own policy and devote sufficient resources toward effective regulation of these hazards.

The subcommittee finds further that CPSC must defer to EPA and other agencies on the basic research aspects of the chronic hazards problem. CPSC's role should be to monitor for the presence of potential chronic hazards in consumer products and conduct short-term research related to potential regulatory action.

We also recommend that Congress consider legislation to formally place a CPSC representative on the Toxic Substances Control Act Committee. This will further encourage CPSC's participation in interagency activities concerning the control of toxic substances.

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[209] See p. 5, this report.

[210] Since its creation, the Commission has taken action on several chronic hazards which have been found in consumer products, including: potentially mutagenic spray-adhesives; lead in paint; asbestos in fireplace logs, and ashes and spackling compounds.

[211] The Consumer Product Safety Act and the Federal Hazardous Substances Act direct the Commission to regulate potentially harmful substances in consumer products. Since chronic hazards posed by chemicals in consumer products may also be defined as "hazardous substances," and substances "which has the capacity to produce personal injury or illness to run through ingestion, inhalation, or absorption through any body surface" (15 U.S.C. 121(g)) and therefore "toxic," the Commission is clearly responsible for further defining what criteria will be used to classify substances for regulatory action.

3. CHILDREN'S SLEEPWEAR STANDARD

The Commission should have acted with dispatch to modify the performance standard for children's sleepwear.

In the spring and early summer of 1976, when questions were being raised about the safety of Tris and other flame-retardant chemicals in children's sleepwear, the Commission was asked to consider amending the children's sleepwear standard to discourage the use of untested flame retardant chemicals.[212]

Several members of the Commission's Flammable Fabrics Act Advisory Committee (the Advisory Committee established to advise the Commission on matters relating to the proper administration of this Act), suggested that the Commission modify the children's sleepwear standard to take the potential danger into consideration pending completion of the National Cancer Institute's carcinogenicity tests on Tris. The Commission's attitude about changing the standard at that time was outlined by Commissioner Kushner in the following colloquy:

> Mr. GORE. You chaired the hearings of the Commission when the Advisory Committee for the Flammable Fabrics Act came before you with one of their periodic reports.
>
> Mr. KUSHNER. I think you may be referring to my having chaired the Advisory Committee itself in one of its meetings at the Commission.
>
> Mr. GORE. That's what I am getting at, right. This was the July 28, 1976, meeting.
>
> * * * * * * *
>
> One of the witnesses is a Ms. Boullieau. She is one of the persons interested in flammability standards who has also expressed concern about the use of chemicals in this field.
>
> * * * I am quoting from page 87 of this document where you said: "Don't you need to wait until the answer is in on Tris before you might want to propose a response to it?"
>
> * * * * * * *
>
> Mr. KUSHNER. Mr. Gore, Ms. Boullieau was asking that the Commission modify its standard in such a way as to eliminate certain tests, because she alleged that if this were done, we could reduce the need for the use of Tris and other chemical flame retardants.
>
> My response was based on the fact that I was reluctant to make any changes in the standard that could reduce the effectiveness of the standard until I knew that that needed to be done.
>
> Mr. GORE. This was July of 1976. This was after the Commission had received evidence that this causes mutagenicity. You had the Ames test then. We have a history of memoranda between the different members of your staff saying that it looks like this may cause cancer, and it looks like it may be mutagenic, and so forth.
>
> You are still saying at that point that you had better wait until the answer is in. What standard of proof do you require?
>
> Mr. KUSHNER. I was simply waiting for what is generally acknowledged to be the best test of carcinogenicity today—that is, the tests that are performed on rats and mice by the National Cancer Insitute.
>
> Those results were not available to us at the time that I made that statement.
>
> * * * * * * *
>
> Mr. GORE. Wasn't there a proposal from them at that time to change the test? To use a different test for general apparel?
>
> Mr. KUSHNER. They were suggesting a different test for wearing apparel generally, . . .
>
> Mr. GORE. I think it's very significant that * * * Ms. Boullieau [who] represented the perspective of a group that had lobbied heavily for flame-retardant standards * * * was very concerned, and rightly so, about the number of young children who were suffering serious burns.

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[212] *Hearings*, supra note 12, at 413.

> * * * that group was able to look at the issue with some commonsense and see that we needed to make some changes in order to take into account the fact that the chemicals being used were, in themselves, dangerous; and that the evidence was available to show that they were very dangerous.[213]

The importance of changing the flammability standard for all chemicals, whether or not Tris was found to be a carcinogen, was brought to the Commission's attention once again in early 1977. In an article entitled "Flame Retardant Additives as Possible Cancer Hazards," Dr. Arlene Blum and Dr. Bryue Ames outlined the danger faced by children wearing chemically treated garments which have not been tested for potential chronic toxicity.

> The risk of the exposure of tens of millions of children to a large amount of a chemical must be balanced against the risk of fire. A calculation (47) suggests that the risk from cancer might be very much higher than the risk from being burned. Flame retardants (and most other large volume industrial chemicals) either have not been tested or have not been adequately tested for carcinogenicity. The use of an untested chemical as an additive to pajamas is unacceptable in view of the enormous possible risks.[214]

The Commission was unmoved by this argument, and action to modify the sleepwear standard was not begun until April 1977. Nevertheless, by October 1977, the Commission had completely reevaluated its position and stated that modification of the children's sleepwear standard was needed to further protect consumers.

> In view of the small number of injuries that appear to be addressed by the requirement for residual flame time, the desirability of reducing the use of flame retardant chemicals in children's sleepwear and the possibility of increasing consumer choice, the Commission believes PP 3–71 should be amended to delete the residual flame time requirements.[215]

The Commission took final regulatory action to amend the children's sleepwear standard in February 1978. The Commission's action came more than 19 months after the Federal Flammable Fabric Act Advisory Committee discussion on the need to modify the standard, and over one year after Dr. Arlene Blum and Dr. Bruce Ames further outlined the need for modifying the standard to further protect the public health.

Moreover, the action by the Commission did not require textile manufacturers to test the chemicals used to retard the flammability of children's sleepwear, nor did it require that all treated sleepwear be labeled with the fire retardant used on the garment.

4. USE OF ADVISORY COMMITTEES

Although members of the Commission's advisory committee on the Federal Flammable Fabrics Act continually raised questions about the children's sleepwear standard and the potential hazard posed by chemical flame retardants in sleepwear, their questions and requests for action were ignored. This situation led, to the resignation of one advisory committee member [216] after his repeated attempts to raise questions about the potential danger posed by flame retardant chemicals in fabrics were frustrated. The difficulties encountered by the members of this committee raise questions about the viability of this advisory committee. If the Commission ignores its questions and suggestions for action, is it an effective body? Should it continue to exist? What influence, if any, does it have on policy decisions?

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[213] Id.

[214] Note 50, supra.

[215] 43 F.R. 4849–4855.

[216] As the record of the subcommittee's hearings on May 11, 1977, indicates, Dr. Kingsley Kay, Professor, Environmental Science Laboratory, Mt. Siani School of Medicine, New York, resigned from the Advisory Committee. Dr. Kay testified that the Commission ignored his attempts to repeatedly raise the issue of dangerous flame retardant chemicals in sleepwear.

> Dr. KAY. I sought membership on that committee. I was not invited.
>
> I must say I was quickly disabused of any ideas that the work we had done at Mount Sinai on fire-retardant chemicals and polybrominated biphenyls in Michigan could be communicated to them because the first thing I heard was that the Flammable Fabrics Act did not apply to the chemicals being used, that the act, indeed, called for meeting certain standards of flammability but the manufacturer was free to meet those however he chose.

The Commission's action concerning Tris indicates that it has not improved its performance in relation to advisory committees since the Subcommittee raised the issue in its 1976 Regulatory Reform report. Moreover, it seems that the Subcommittee's 1976 criticism that the Commission has "not permitted advisory committee's to live up to their potential as an avenue for consumer contributions to Commission decision-making" is still valid.[217]

The subcommittee believes that the Commission must consider the questions raised by members of this advisory committee and more vigorously explore actions proposed by advisory committee members.

5. NEED TO INVESTIGATE

The subcommittee also finds that the Commission's early reluctance to modify the flammability standards illustrates its unwillingness to investigate problems until they become critical. Exploration of ways to modify the standards could have been undertaken in early 1976. If this had been done, changes in the standard may well have been ready at a much earlier date. Not only would the manufacturers of Tris-treated garments have been halted earlier, but the economic impact of the Tris ban on garment makers and others would have been greatly reduced.

The subcommittee also finds that the Commission needlessly waited for the results of the NCI Tris tests before it began action to modify the sleepwear standards. This action unnecessarily delayed action to reduce consumer exposure to Tris and other flame retardants in children's sleepwear. Moreover, although the Subcommittee believes that the new standards afford consumers greater protection, we believe all garments treated with flame retardant chemicals should be labeled with the chemical used. We encourage the Commission to reconsider its action to require such labeling.

That really summarizes my first meeting of two with them.

Shortly after that meeting, which was last July, the correspondence with that committee, which is voluminous, in fact overwhelming, began to show that they were considering doing something about Tris, that they were really keeping their eye on it as a chemical, but at that point they had decided to wait until this coming summer to get the result on the cancer test.

As I said before, and as I wish to repeat here, there was apparently no thought given to taking any action on the basis of Tris being a mutagen.

For the second meeting, we were invited to present subjects for discussion. I suggested a broad discussion which would be contributed to by their own toxicology staff, a broad discussion of fire retardants, knowing, as I have shown this morning, that there were many other candidate materials. This never appeared on the agenda of the second meeting for reasons which I have not discovered.

At that point, I felt I was not contributing anything so I left the committee.

Mr. WAXMAN. You resigned from the committee?

Dr. KAY. I resigned from the committee because my knowledge was of no evident value. I was certainly not making any impression on them without resorting to hysterics of some kind, which I was not prepared to do.

Hearings, supra note 12, at 66–67.

[217] Note 3, supra at 219.

IX. Industry's Handling of the Tris Matter

A. Tris Production

The Michigan Chemical Co. (MCC) a subsidiary of Velsicol Chemical, Northwest Industries since December 1976, began producing Tris in July 1958.[218] In the early 1960's, Tris was used as a flame-retardant in castacrylic sheet, polyurethane foam and polystyrene foam.[219] A higher grade, purer form of Tris for use in acrylic fiber was first produced in 1963.[220]

Michigan Chemical Co. (MCC) was the largest producer of Tris during the last decade. Michigan produced over 54 million pounds of both the high grade Tris (LVT23P) and the lower grade Tris (T23P) between 1967 and 1977.[221] Sales of the higher grade Tris increased substantially with the promulgation of the children's sleepwear standard in 1972 because it was extensively utilized by textile mills to flame retard polyester, acetate and triacetate fibers and mixtures of these fibers.[222]

B. Safety Testing of Tris by Michigan Chemical Co.

In 1967, Michigan Chemical contracted with International Research and Development Corporation (IRDC) for tests to determine comparative subacute dermal toxicity and blood bromide concentrations of Tris in albino rabbits. These tests indicated that both forms of Tris were absorbed through the skin when applied to the surface skin of rabbits.[223] The report concluded that "both (Tris) compounds exhibited a dose-related penetration through the skin as revealed by the blood bromide analysis." [224]

Another study carried out for Michigan Chemical Co. by the WARF Institute, Inc. (Wisconsin Alumni Research Foundation) dated December 1972, concluded that "Tissue residue data for groups receiving samples 4882 (Tris) indicated very high residues in muscle, liver and fat at zero withdrawal." [225] These results demonstrated that, the bromine in Tris may be stored in body tissue.

In 1974, MCC began to promote actively the use of Tris in children's sleepwear.[226] Although it conducted a literature search and more than 16 safety tests on the acute toxicity of this chemical, it did not conduct any special studies to determine whether Tris might pose a chronic hazard to children.[227]

However, Michigan Chemical became aware in November 1975 that Tris was a mutagen under the Ames test.[228] It also knew that Tris had been found to be highly toxic to fish; [229] that it was easily absorbed in fish tissue, that it was a colinesterase inhibitor in fish at extremely low levels;[230] and, that it was under test by NCI as a suspected carcinogen.[231]

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[218] *Hearings*, supra note 12, at 92.
[219] Id. at 90.
[220] Id. at 92.
[221] Id.
[222] Id. at 91.
[223] *Hearings*, supra note 12, at 96–97.
[224] Id.
[225] Id. 96.
[226] Id. at 94.
[227] Id. at 97.
[228] Id at 98.
[229] Id at 245.

Upon receiving the mutagenicity information, MCC contracted with Litton Bionetics for tests designed to either confirm or contradict findings that Tris was a potent mutagen in bacterial systems and therefore potentially carcinogenic and dangerous to man.[232]

MCC also issued a letter, dated March 17, 1976, to its Tris customers. The letter did not warn customers that Tris might be potentially dangerous,[233] but simply stated that although some preliminary tests raised questions about Tris, MCC indicated there was no reason to be alarmed and was investigating to be "sure there is no indication of potential hazard to our workers, suctomers or consumers." [234] The letter stated:

> Michigan Chemical Corporation has extensively investigated the potential toxicological hazards posed by this product. The results of these findings have been published, and indicate that Tris (2,3-dibromopropyl) phosphate possesses a low order of toxicity via oral, dermal, and inhalation modes of exposure. The low order of toxicity has been corroborated by the absence of any complaints of toxicological problems from the use of this product.
>
> Recently it has come to our attention that tris (2,3-dibromopropyl) phosphate shows a positive response in a prescreening experimental microbiological test for mutagenicity and carcinogenicity.
>
> While *we do not believe that these experimental test results are any reason to be alarmed, we want you to know that we are pursuing this matter to make sure there is no indication of potential hazard to our workers, customers or consumers. We will keep you informed.*[235] (Emphasis added.)

Litton Bionetics transmitted its first written report to Michigan Chemical in July 1976 concluding that Tris was indeed a mutagen in the Ames Test, and at least one other mutagenicity test.[236] Litton continued to test Tris for mutagenic activity, reporting additional mutagenicity test results to MCC. A final report on the tests conducted by Litton was completed in February, 1977.[237] These tests, which confirmed that Tris was a mutagen in several test systems, were received by Michigan Chemical in draft form in October 1976, but were not released to the public until the subcommittee's May 1977 hearing.[238]

In testimony before the subcommittee, Dr. Frank Daniher, Director of Research for Industrial Chemicals and Resins for MCC, indicated that MCC had been aware of all of the outside research on Tris, but was not convinced that there was a danger to human health.[239]

Moreover, in reaction to the filing of EDF's March 1976 petition to label Tris-treated sleepwear, MCC had submitted a memorandum to the Consumer Product Ssfety Commission opposing labeling and stating in part that:

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[230] Id at 247–250.

[231] Id at 372.

[232] Id at 98.

[233] *Hearings*, supra note 12, at 97. See testimony of Dr. Paul Hoffman.

[234] Letter from M. L. Garman, Vice President, Michigan Chemical Co., to Tris customers, Mar. 17, 1976. *Hearings*, supra note 12, at 95.

[235] Id.

[236] Letter from David Brusick, Litton Bionetics, to Dr. Frank A. Daniher, Michigan Chemcial Co., July 30, 1976. *Hearings*, supra note 12, at 229–232.

[237] Litton Bionetics, Inc., "Mutagenic Evaluation of Tris Final Report" submitted to Velsical Chemical Corp., Feb. 18, 1977, at 113. *Hearings*, supra note 12, at 111–125.

[238] *Hearings*, supra note 12, at 119.

[239] Id.

> Tris does not pose a mutagenic or carcinogenic hazard.[240]
> There are no results to indicate that Tris presents either a mutagenic or carcinogenic hazard as used in flame retardant fabrics.[241]

* * * * * * *

and,

> On the basis of considerable commercial experience and extensive research, the company believes that Tris presents no health hazard to consumers, and that the need for labeling as proposed in the EDF petition is not supported by scientific evidence.[242]

Michigan Chemical also received, by November 1976, a copy of the Prival letter to CPSC dated October 20, 1976, containing additional study findings indicating that Tris was potentially dangerous.[243]

In December 1976, Dr. Daniher reasserted publicly that EDF's request was "not supported by scientific evidence" and that Tris did not "pose a mutagenic or carcinogenic hazard." [244] Dr. Daniher's December presentation, which was essentially the same as that presented to the Consumer Product Safety Commission in July 1976, did not mention all the results of the short-term mutagenicity tests conducted for MCC by Litton Bionetics.

In February 1977, MCC decided to "voluntarily withdraw Tris from the apparel market." Although no full explanation was given for this action, Michigan Chemical representatives informed the Subcommittee that the decision was due to "* * * a gradual decline (in the sales of Tris) in 1975 and a more pronounced decline in 1976." [245]

C. Findings and Conclusions

1. Michigan Chemical Co. failed to conduct proper safety tests on Tris although it promoted its use in children's sleepwear.

In testimony before the subcommittee last May, Dr. Paul Hoffman, Chairman and Chief Executive Officer of Velsicol Chemical Co., assured the subcommittee that once MCC knew that Tris was being utilized for flame retarding children's sleepwear, it had taken all necessary action to determine whether Tris was hazardous. Subsequent testimony indicated, however, that MCC did not conduct chronic hazard studies on Tris until 1976, approximately 2 years after it began actively marketing it for use in children's sleepwear, and more than 3 after it knew Tris was being used for this purpose. In the following colloquy, Congressman Henry Waxman (D-Calif.) questioned MCC about its testing of Tris.

> Mr. WAXMAN. Between 1972 and 1976, when Tris was being used as the major retardant in children's sleepwear, did you conduct any skin absorption tests, long-term feeding studies, or other tests along these lines?
> Dr. DANIHER. No.
> Mr. WAXMAN. You did not?
> Dr. DANIHER. The only test of any duration was the 28-day test by WARF dated December 22, 1972.
> Mr. WAXMAN. You knew it was being used in children's sleepwear, that children were wearing these fabrics for perhaps 12-hours a day, and that these children were in effect being wrapped and bathed in material which can be absorbed through the skin.

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[240] Memorandum for the U.S. Consumer Product Safety Commission on the Safety of the Flame Retardant Chemical Tris, by the Michigan Chemical Co., July 12, 1976, at 8.
[241] Id at 9.
[242] Id at 1.
[243] Id. at 237.
[244] *Hearings*, supra note 12, at 235.
[245] Id. at 91.

Dr. DANIHER. At that time I do not believe there was any evidence to support that Tris was absorbed from a treated fabric.[246]

There was experimental evidence as early as 1967 suggesting that Tris painted on the skin of rabbits could be absorbed.[247]

Although acute toxicity tests were conducted on Tris, simple and inexpensive tests designed to determine whether Tris was a potential mutagen were not conducted in the period 1971 to 1976. Mutagencity tests were begun only after Michigan Chemical Co. had received the Rosenkranz mutagenicity test results from EPA.[248] The subcommittee believes that if proper mutagenicity studies had been conducted by MCC before it began promoting the use of Tris in sleepwear, the potential hazard posed by Tris might have been discovered at an earlier date.

Not only did Michigan Chemical fail to conduct proper chronic hazard tests on Tris before it was promoted for use in children's sleepwear, but it also failed to seek advice from government scientists about the toxicity of Tris. Although Dr. Hoffman indicated that Michigan Chemical conducted a full search of the scientific literature on Tris toxicity before MCC began promoting Tris for use in sleepwear,[249] Dr. Frank Daniher stated that Michigan Chemical Co. did not even know, until late 1975, that Tris was being tested by the National Cancer Institute (NCI) for potential carcinogenicity.

Mr. WAXMAN. Let's go along the chronologic order. In 1973 the National Cancer Institute put Tris on its bioassay list to be tested for carcinogenicity. Were you aware that it was put on the NCI list in 1973?

Dr. DANIHER. No.

Mr. WAXMAN. Is it not a matter of public record when the National Cancer Institute puts a product on its list for bioassay study?

Dr. DANIHER. It may be, yes.

Mr. WAXMAN. Let me assure you that it is a matter of public record that the National Cancer Institute put your company's product on their bioassay list.

Why did your company not inform itself of that fact and try to discover on its own whether there was a danger?

Dr. HOFFMAN. The first that we knew of the NCI work was in December of 1975.[250]

According to NCI, Tris was placed on the carcinogenicity test list as early as 1973 and the long-term feeding studies were begun in July 1974.[251]

The subcommittee believes that if MCC had conducted a thorough review of toxicology data on Tris, it would have discovered that the chemical was under test by NCI. The fact that Michigan Chemical learned that Tris was under test for the first time in a telephone conversation with EPA staff in late 1975 [252] suggests that MCC's efforts to acquire all available scientific information on Tris was not very thorough.

The subcommittee finds that Michigan Chemical Co. did not conduct proper safety tests on Tris once it knew Tris was being used in children's sleepwear. The fact that MCC knew that Tris-treated sleepwear was being worn by millions of children for extended periods of time and yet did not conduct either a thorough review of scientific thinking on Tris or carry out chronic hazard and skin absorption tests indicates that the company did not exercise proper caution in promoting the use of Tris.

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[246] Id. at 97.
[247] Id. at 96–97.
[248] Id. at 98–99.
[249] Id. at 93.
[250] Id. at 97–98.
[251] Note 81, supra.
[252] *Hearings*, supra note 12, at 98.

The Subcommittee believes that the Ames and/or other short-term mutagenicity tests should be conducted on compounds proposed for use in consumer products before companies make a large investment in them. If a chemical is mutagenic under the Ames and/or other short-term mutagenicity tests, and if the chemical may be ingested, inhaled, or absorbed through the skin of workers or consumers, then, we believe that companies should strongly consider withholding the product from production. If the product is already being produced, and it exhibits mutagenicity and can be absorbed, inhaled or ingested, it would be prudent to cease production until additional chronic hazards tests are performed to resolve the safety issue. These preventive measures, if faithfully employed, should further limit the number of potentially dangerous compounds in production and further reduce the need for action to ban products already in use.

2. Michigan Chemical Co. made misleading statements to the Commission and the general public; failed to disclose all the information it had in its possession on the toxicity of Tris; and, failed to heed warning signs about the potential toxicity of Tris.

Michigan Chemical Co. financed several studies on the acute toxicity of Tris.[253] However, as pointed out in the previous chapter, it conducted no tests, until 1976, to determine whether Tris might pose a chronic hazard.

Although test results from some early acute toxicity studies conducted for Michigan Chemical Co. suggested that there might be a problem, MCC scientists were not concerned about the findings. The following colloquy is illustrative:

Mr. Waxman. I want to go over some points in chronology to ascertain what information you gave to your customers and what information you pursued on your own to discover whether there would be adverse health effects.

I believe in 1967 Tris was found, in studies commissioned by your company, to be absorbed through the skin. Is that correct?

Dr. Hoffman. I will ask Dr. Daniher to respond to that.

Dr. Daniher. Yes.

Mr. Waxman. And in 1972, Michigan Chemical Co. received a report from the WARF Institute indicating the presence of residue in high levels in fat tissues, liver, and muscle of animals. Is that correct?

Dr. Daniher. Yes, sir. I would like to add that those residues rapidly abated, indicating that the chemical was not persistent biologically.

Mr. Waxman. But in the 1967 Michigan Chemical report by Dr. Wazeter, director of research, it stated:

> At the 1.0 g/kg dosage level, bromide was found present in the blood in three of the four rabbits after 7 days of treatment. After 14 days of treatment all rabbits in this group exhibited the presence of blood bromide.

Again quoting:

> Both (Tris) compounds exhibited a dose-related penetration through the skin as revealed by the blood bromide analysis.

Is that correct?

Mr. Daniher. Yes.

Mr. Waxman. So in 1967, you had information that Tris could be absorbed through the skin and that, at least to some extent, there was detectable residue in the tissue, muscle, and liver.

My question to you is this: Wasn't this 1967 evidence a sufficient red flag in your mind that perhaps some additional studies ought to be conducted to decide whether serious health consequences were present?

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[253] Some of the studies conducted by Michigan Chemical Co. are contained in *Hearings*, supra note 12, at 100–232.

Dr. **Daniher.** You have to take into account the study which was conducted which indicated skin absorption. That was painting of pure undiluted material onto the skin of an animal. This is totally different in its exposure than a fabric which is impregnated with the chemical.

I believe if you will refer to data which we published in the latter part of 1976, you will see that the modes of exposure and potential absorption are vastly different.[254]

As the above testimony indicates, Michigan Chemical Co. did not believe that the test results provided a sufficient "red flag" to warrant further testing to determine whether Tris might pose a chronic hazard.

Michigan Chemical Co. did not begin examining Tris for potential chronic toxicity until early 1976. Its first action in this regard was to provide Dr. Rosenkranz with samples of purified Tris for testing under the Ames test.[255] After testing the material several times Dr. Rosenkranz concluded that is was definitely mutagenic.[256] In March 1976, Litton Bionetics began, under an MCC contract, to test samples of Tris for potential mutagenic activity. Preliminary results of these tests were available in July 1976.

While Litton was in the process of testing Tris for mutagenicity and tumor induction, Michigan Chemical sent a letter to its Tris customers advising them that it was investigating "to make sure there is no indication of potential hazard to our workers, customers, or consumers." [257] The letter also stated that Michigan Chemical Co. would keep its customers informed of its findings.

The first written report [258] on the work being conducted by Litton Bionetics on the chronic toxicity of Tris was transmitted to Michigan Chemical Co. on July 30, 1976. Dr. David Brusick, Director, Department of Genetics, Litton Bionetics, informed Dr. Frank Daniher, Director of Research for Industrial Chemicals and Resins, that these test results indicated that Tris was a mutagen in several different test systems under different conditions. Dr. Brusick wrote:

> In summary, the data thus far obtained with TRIS show that the chemical is mutagenic for *S. typhimurium* strains TA–1535 and TA–100. Tests with liver microsomes in the Ames procedure show strong mutagenicity at concentrations of 10 ug to 500 Hg per plate. Indications of weak mutagenicity were obtained in microsome activation tests conducted in L5178Y (TK+/−) mouse lymphoma cells.
>
> *Fabric treated with TRIS was found to have mutagenic activity* for TA–1535 when placed in proximity to the bacteria with rat liver microsomes, but tests in which TRIS treated fabric was placed in contact with shaved rate for 24 hours/day over five consecutive days, shows no significant levels of mutagen in collected urine (some tests are being repeated). Oral and dermal *administration of TRIS at 500 mg/kg or higher, however, produced measurable levels of mutagen in the urine collected over five days.* Greatest activity was found in orally administered TRIS with reduced activity in the dermal treatment. Dermal applications lower than 500 mg/kg (125, 275, 400 mg/kg) appeared to have no measurable mutagens in the urine although some of these tests are being rerun in part.[259]

Although MCC had told its customers that it would keep them informed, it did not transmit this information to them.

The test results provided to MCC by Litton Bionetics raise significant questions about the objectivity of MCC's July 12, 1976, memorandum filed with the Consumer Product Safety Commission. That memorandum argued against the March EDF petition to place a warning label on Tris-treated sleepwear, and stated in part that:

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[254] *Hearings*, supra note 12, at 96–97.

[255] Id. at 98.

[256] Id.

[257] Id. at 95.

[258] It is entirely possible that this information, since some of it was presented to the Commission on July 12, 1976, was transmitted earlier either by telephone or through some other informal written memorandum.

[259] *Hearings*, supra pote 12, at 231.

> * * * There are no results to indicate that Tris presents either a mutagenic or carcinogenic hazard as used in flame retardant fabrics.[260]

Furthermore, it concluded that:

> 1. No data exist to support the claim that Tris is absorbed through the skin from a treated fabric.
> 2. Tris may be ingested in small amounts by infant mouthing habits. The maximum amount that realistically could be ingested by this means is more than a thousand fold lower than the dose required to give a mutagenic effect.
> 3. *There are no data to support the claim that Tris poses any toxicological or neurotoxicological hazards.*[261] (Emphasis added.)

The memorandum also references studies by Litton Bionetics showing that Tris did not cause a mutagenic effect in some tests.[262]

Michigan Chemical did not include in its memorandum Litton's results indicating a positive mutagenic Ames test and positive mouse lymphoma cell mutagenicity test. It also failed to mention the finding that mutagenic activity was found when test bacteria were exposed to Tris-treated fabric. Further, although a copy of MCC's memorandum opposing EDF's petition was transmitted to its customers, via letter dated July 26, 1976, that letter failed to reflect the above findings by Litton Bionetics.

Additional information on the potential hazard posed by Tris was transmitted to MCC in the form of a report from Litton Bionetics on October 29, 1976. This report stated:

> Tris induced transformed foci in a clowed line of BALB/3T3 cells at the concentration of 0.05 ppm and *was evaluated as being positive under the conditions of this malignant transformation assay.*[263] (Emphasis added.)

Although these findings indicated that Tris was a potential "tumor inducer", Michigan Chemical did not take action to inform CPSC, its customers, or anyone else of this significant finding. In the following colloquy, Dr. Daniher states that no action was taken by Michigan Chemical Co. because the information was in a "draft" report.

> Mr. Waxman. By October of 1976 you received your report from Litton Bionetics.
>
> Dr. Daniher. Correct.
>
> Mr. Waxman. That report concluded:
>
>> Tris induced transformed foci in a cloned line of BALB/3T3 cells at a concentration of 0.05 ppm and was evaluated as being positive under the conditions of this malignant transformation assay.
>
> In other words, Tris was a mutagen. You were convinced of that in October of 1976, were you not?
>
> Dr. Daniher. That particular test that you refer to is not, as I understand it, a test for mutagenicity but a test for tumor induction.
>
> I do not think that I am sufficiently knowledgeable to really say whether there is a difference between tumor induction and mutagenicity from a fundamental viewpoint.
>
> Mr. Waxman. Did that test cause you to be concerned about possible adverse health effects from Tris?
>
> Dr. Daniher. The report that you are citing is a draft report. The data which is presented in that report is in our opinion ambiguous, inconsistent with available literature data on the behavior of a chemical in that type of test.

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[260] Note 60, supra, at 9.

[261] Id. at 13.

[262] Id. at 8.

[263] *Hearings*, supra note 12, at 127.

To gain more information as to whether or not those results were valid, we commissioned further studies.[264]

On November 21, 1976, Michigan Chemical Co. received more information on the potential danger posed by Tris.[265] Nevertheless, when Dr. Daniher presented his paper to the Tenth Annual Meeting of the ICFF in New York in December 1976, his paper did not include the additional findings by Litton Bionetics, nor did it cover the new information supplied by other scientists. He essentially presented the same statement that he had presented to the CPSC in July 1976. And, like the July memorandum, Dr. Daniher's remarks were distributed to Michigan Chemical Co.'s Tris customers.

In January 1977, the preliminary data from the National Cancer Institute on the potential carcinogenicity of Tris was available.[266] These data included animal tumor data printouts indicating what the pathologists had discovered when the test animals were sacrificed and examined. These data indicated that Tris was a carcinogen in animals.[267]

Testimony before the Subcommittee indicates that the MCC could have gained access to these data soon after the first of the year.[268] Although it is not known whether Michigan Chemical did indeed obtain these data, it is known that on February 3, 1977, MCC "voluntarily withdrew Tris from the apparel market." [269]

Following the "voluntary withdrawal," MCC received a final report form Litton Bionetics. The Report dated February 18, 1977, stated:

> * * * *the collective data shown (sic) that "TRIS" has the properties characteristic of a chemical mutagen.* It was mutagenic in bacteria strains G–46, WP_2 *uvrA*– and TA–1535 with *in vitro* metabolic activation and TA–1535 at high concentrations without *in vitro* activation. At high concentrations (500 mg/kg–5000 mg/kg), it was found that sufficient levels of genetically active "TRIS" were excreted from rats exposed by oral or dermal routes. Results of mutation studies in cultured mammalian cells were inconclusive but suggestive of a weak response at concentrations near 5 ppm. Since well defined human absorption and exposure levels of "TRIS" are not available, *the present set of results indicates that some (although unqualified) level of risk is associated with "TRIS" use in the environment.*[270] [Emphasis supplied.]

This information, which would have assisted the CPSC in making regulatory decision on Tris, was not transmitted to the Commission.

In summary, the subcommittee believes that the record demonstrates a failure on Michigan Chemical Co.'s part to:

1. Heed the warning signs about the potential adverse effects of Tris; and
2. Report significant findings to the CPSC and general public.

The subcommittee also finds that statements made by Michigan Chemical Co. officials about the safety of Tris were at the very least misleading in the face of the scientific evidence presented by outside scientists and the tests conducted for the company itself. Moreover, the subcommittee believes that Michigan Chemical Co. withheld information from the public and the CPSC which might have brought about a more speedy resolution of the Tris health risk question.

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[264] Id. at 234–234.

[265] Id. at 237.

[266] The first printouts showing the results of the animal feeding experiments were dated Dec. 29, 1976. The Environmental Defense Fund's February 1977 petition to ban Tris in sleepwear was based upon its review of January 1977 test data from NCI.

[267] Note 81, supra.

[268] *Hearings*, supra note 12, at 242.

[269] Id. at 91.

[270] Id. at 119.

ADDITIONAL VIEWS OF THE HONORABLE HENRY A. WAXMAN

I strongly concur with the subcommittee's report and findings. The report is a meticulous documentation of the CPSC's inability to react in a timely manner to a clear and irrefutable health threat. The CPSC's efforts to protect the public from the health risks of Tris resulted in what can only be described as a regulatory nightmare. The entire episode reflects poorly upon the Commission's administrative, scientific and legal judgment.

Notwithstanding my endorsement of the subcommittee's recommendations, I am sorry the report did not include an analysis of the Commission's efforts to control the export of Tris following the April 1977 ban. While I recognize it was the subcommittee's intent to focus upon Tris as it related to development of a chronic hazards policy, the export issue is closely related to domestic regulation.

In fact, in acting to prevent the sale of Tris, the CPSC was actually responsible for creating an export market for the banned garments. It would have been appropriate for the subcommittee to review the adequacy of the CPSC's efforts to minimize the health risks resulting from Tris exports.

Over 16 months have passed since the Commission initiated action to end the sale of Tris treated sleepwear. Numerous press accounts have documented the export of several million dollars worth of the banned garments. These overseas sales were deliberate efforts by U.S. manufacturers to recoup a portion of their losses resulting from the CPSC ban. The majority of the exports were shipped to Third World countries where product safety laws are less strict and the expertise to evaluate chronic hazards unavailable.

Just as it is intolerable that the United States would permit cancer causing sleepwear to be sold to American children, it is equally repugnant that U.S. manufacturers would be permitted to sell these same garments to consumers overseas. Products hazardous to American children are no less hazardous to foreign children.

Despite ample knowledge that Tris sleepwear was being shipped overseas, the CPSC failed to make more than pro forma efforts to notify foreign governments of the possible health risks. This is inexcusable.

The United States is generally recognized as having the most sophisticated product safety laws and research methods in the world. Accordingly, many less developed nations look to the United States for guidance in establishing product safety standards to protect the health of their citizenry.

From April 8, 1977 until May 5, 1978, the CPSC adopted a laissez-faire attitude toward Tris exports. In fact, on October 20, 1977, the Commission issued a policy statement concluding that they lacked authority to prevent the export of Tris sleepwear. This policy permitted the successful export of hundreds of thousands of cancer causing garments to unsuspecting foreign consumers. At no time did the CPSC make an active effort to inform foreign governments of the possible health risks posed by these U.S. exports.

On May 5, 1978, a newly constituted CPSC leadership reversed the October 20, 1977, export policy decision and voted to prohibit the export of Tris treated sleepwear. While the May action was noticeably belated, it does signal the emergence of a CPSC more committed to public health and product safety. Further, it is a recognition that product safety decisions in this country may have significant effects on the health of citizens who purchase U.S. exports.

Although the CPSC's Tris export policy affects only products regulated under the Federal Hazardous Substances Act, it establishes an important precedent which should be incorporated in the other statutes administered by the agency.

It must be noted, however, tha tthe Commission has not enacted a comprehensive policy toward the export of products which violate U.S. product safety law. The Commission's confused and contradictory activity in the Tris case is a persuasive and compelling argument for a uniform policy in this area. Despite the very serious dangers implicit in the export of banned products like Tris, the Commission has yet to develop a procedure for prohibiting the export of banned products previously introduced into domestic commerce and informing foreign countries of U.S. product safety decisions.

The Tris case has served to focus public attention on U.S. export policy. I am hopeful the subcommittee will have the opportunity to assess and evaluate the adequacy of the CPSC's existing export policy. The Commission must be urged to focus attention on this important area and develop a comprehensive policy toward consumer product exports.

The CPSC's export policy is of critical importance both to effective domestic product safety regulation, as well as to this country's reputation in the international community.

SUPPLEMENTAL VIEWS OF THE HONORABLE JAMES M. COLLINS, NORMAN F. LENT, AND MATTHEW J. RINALDO

The purpose of these views is to bring to the attention of the Congress and the American people two of the very real problem areas that we learned of as a result of our inquiry into the Tris debacle. This will not, of course, be a total catalog of problem areas, but simply those most glaringly presented by the facts in this case.

The first area that we would like to point out is the question of the multiple statutes which the Consumer Product Safety Commission (CPSC) is called upon to administer and enforce. The Commission currently has five such acts under its purview. In addition to the Consumer Product Safety Act, it has the Federal Hazardous Substances Act, Flammable Fabrics Act, Refrigerator Safety Act and the Poison Prevention Packaging Act.

The existence of these five separate acts, some of which have comparable provisions, has led to confusion as to which provision of which act to utilize to take a regulatory action. A clear example of this problem is found in the subcommittee report wherein the report is critical of the Commission for utilizing the Federal Hazardous Substances Act instead of the Consumer Product Safety Act (CPSA) in bringing its action to ban Tris. Perhaps, as the subcommittee report indicates, it would have been better to use the CPSA, looking at the issue in retrospect which is clearly one of our duties as members of this subcommittee. An even greater duty in our minds is to recommend ways to avoid problems of a similar sort in the future.

One effective way of eliminating the problems associated with determining which provision of which act to use in a given situation is to consolidate the statutes into one act. The Commission has now been in operation for 5 years, and by any standard of measurement, it has not performed well. One of the problems may well be, however, that the Congress built some of these weaknesses into the system when the Commission was created. What we believe needs to be done is to take a fresh and hard look at the legislation dealing with the Commission and remedy the deficiencies that may well have been due to faulty design. Certainly, consolidation of the statutes into one cohesive body of law would eliminate at least some of the confusion that now exists. If this consolidation were accomplished, there would be no question about which provision to use because there would be only one provision.

We would now like to address what we consider to be a far broader and more important question, that of chemicals and government coordination of the testing of toxic chemicals. At the present time, we have a multiplicity of Federal agencies engaged in this type of activity, and the performance of each has been on an uneven and ad hoc basis. We believe that this situation demands a much more uniform approach to a very large problem. A major step forward in this area was the Interagency TSCA Committee established by section 4(e)(2)(A) of the

Toxic Substances Control Act, and we agree with the subcommittee report's recommendation that legislation should be considered to include a CPSC representative on that panel. Much more, however, needs to be done.

In this area of testing of chemicals, we see as a major problem the tests themselves. There seems to be no general consensus in Government, nor in the scientific community, concerning the reliability of the existing tests and their applicability to human beings. There is as we see it a critical need for a reliable and generally acceptable series of tests for the screening of chemicals. The emphasis to date has been on testing chemicals, but if the tests are unreliable or lack scientific concensus, testing alone is inadequate and will bring this effort into serious disrepute.

We must in some fashion enhance the development of screening tests, test protocols and screening procedures which are reliable, fast, and cheap. The costly and lengthy animal studies of the sort which led to the banning of Tris are simply inadequate. We do not believe that this effort to develop quick and reliable tests is the type of thing that should be performed by the CPSC but should be the job of the Environmental Protection Agency (EPA). Somebody needs to be put in charge of this effort of identifying and regulating toxic chemicals, and we believe that the TSCA gives the EPA the authority to move ahead in arriving at the type of consensus which we feel is needed. If EPA were to make progress in this area, it would be of immense benefit to other agencies of the Government such as the CPSC which is also charged with the responsibility of regulating such chemicals.

James M. Collins.
Norman F. Lent.
Matthew J. Rinaldo.

SEPARATE VIEWS OF HON. JAMES M. COLLINS

I take this opportunity to comment separately on the question of Tris and the children's sleepwear standard, because I have been deeply interested in this subject for well over 2 years now. In the year, 1976, I wrote to then Consumer Product Safety Commission (CPSC) Chairman, Richard Simpson, expressing my grave concerns about the flammability requirements for children's sleepwear. My first letter to Chairman Simpson was in March 1976. and the Commission response to me was a tersely worded letter and a copy of a Commission press release. I wrote once again to the Commission Chairman in August 1976, sending to him a copy of a letter that I had received from Dr. William J. Rea of Dallas on the subject of fire retardant pajamas.

Dr. Rea's letter to me was very instructive in that he recounted the adverse effects of exposure to flame retardant pajamas to his own family and to five of his patients. Dr. Rea identified such problems as skin rashes, dizziness, acute asthma attacks, recurrent sore throats, hyperactivity, swelling of eyes, feet, and hands, as well as recurrent headaches, all of which were directly and conclusively linked to children's sleepwear which was chemically treated to make them flame resistant.

The Commission's response to my second letter and Dr. Rea's findings was to send to me another of their press releases about loop labels carrying care instructions. The Commission's point was that these labels should be clearly visible. Apparently, no one at the Commission read my letter nor Dr. Rea's, because we wanted the chemicals removed from children's pajamas due to the fact that they were harming their users. The Commission, however, was concerned with how best to wash these garments to retain the chemicals.

Of course in 1976 neither Dr. Rea nor myself was aware that Tris, the principal flame retardant, was a possible carcinogen. This information was to come later, but even with the banning of Tris, chemicals can still be used to make children's sleepwear flame resistant. The children's sleepwear standard is still in effect.

Shortly after my last communication with the Commission, it became known that the National Cancer Institute's bio-assay tests had shown Tris to be a carcinogen in tests with laboratory animals, and these tests led to the banning of Tris and our subcommittee hearings.

After our subcommittee hearings in May 1977, I pursued in depth the background which led up to the development of the sleepwear standard. My concerns at this time were that although Tris had been banned, the sleepwear standard requiring the continued use of flame retardant chemicals was still in place. Additionally, as a matter of public policy, I was interested in how the Commission determined in what instances a standard should be promulgated.

In studying how the sleepwear standard came into being, my reaction was one of sheer incredulity. I learned that in 1967, prior to the creation of the Consumer Product Safety Commission, the power to make standards under the Flammable Fabrics Act was given by legislation to the Department of Commerce.

Pursuant to its authority under the Flammable Fabrics Act, the Department promulgated the first children's sleepwear standard on July 29, 1971, for sizes 0–6X. The first significant thing that I uncovered about the development of this first standard is that the Department of Commerce had in its possession no reliable data of deaths or injuries from sleepwear fires. The point is that the Government undertook to mandate a standard before it even knew the magnitude of the problem that it was seeking to address or even if a problem of any magnitude even existed.

Former CPSC Commissioner Kushner, who was at the National Bureau of Standards at the time of the adoption of this standard, confirmed during our subcommittee's October 3, 1977, hearing that no such data existed. The Commerce Department, thus, proposed a solution to a problem which required the chemical treatment of sleepwear for which there was no data to show that the problem even existed. Even more disconcerting is that former Chairman John Byington admitted at that same October 3, 1977, hearing that the Commission still has no such data.

The second troublesome thing that I learned was that on April 29, 1971, 3½ months before the standard was initially adopted, the Department of Commerce was warned by the American Textile Manufacturers Association (ATMA) not to take hasty action on the adoption of this standard without adequate time to allow for allergic or toxicity tests. In their comments on the proposed standard to the Secretary of Commerce, the ATMA said the following:

> It would be a grave mistake and a serious setback for progress in fire-resistant textiles if, through hasty action, large numbers of children were *exposed to fabrics which caused skin rashes and other allergic or toxic reactions.* (Emphasis Added)

As the above quotation indicates, what the ATMA warned might happen did in fact happen, because what Dr. Rea found in Dallas were clearly allergic and toxic reactions to chemicals in sleepwear. The ATMA was, of course, at this point in time (1971) concerned with the toxic and allergic problems as Dr. Rea and myself were to become after several years of actual experience with the standard.

A third point, which I discovered and which our subcommittee's hearing record now confirms, is that when the standard was put into effect Tris was the only known treatment for polyester that would make that fabric flame retardant. Thus, the Government in effect compelled the use of Tris to overcome a problem which they had no data to show even existed. This is in spite of the fact that the Flammable Fabrics Act requires that in order to set a standard a finding must be made that it is needed to adequately protect the public against an unreasonable risk of the occurrence of fire leading to death, injury, or significant property damage. This requirement was apparently all but ignored by the Department of Commerce when it promulgated the first standard, because there was not a shred of hard data upon which to base such a finding.

When the Consumer Product Safety Commission was established in 1972, jurisdiction over the Flammable Fabrics Act and the children's sleepwear standard was transferred to it. The CPSC has perpetuated this standard and there is still no reliable information indicating that it is necessary to prevent or reduce an unreasonable hazard to children.

From my standpoint, I believe that several things have been learned from the Tris experience. The first is that never again should the CPSC nor any other agency of the Federal Government be permitted to put into effect a standard until such time as they have reliable data showing that a problem really does exist.

Second, I would say that once it has been shown with hard data that there does exist a problem that the remedy specified be shown to be both safe and effective. By safe and effective, I mean to say that we do not want another Tris-type situation where in an effort to address one perceived problem that an even more potentially grave situation results.

Third, I believe that this situation points out the need for better and more reliable information on consumer product safety hazards. The current system utilized by the CPSC, "National Electronic Injury Surveillance System" known as NEISS is in my opinion totally invalid, completely useless, and a gigantic waste of taxpayer money. Under this system, information is collected from 119 hospital emergency rooms, but the system does not provide information on causation. If, for instance, a child is riding his bike and is hit by an automobile, this accident would be reported as a bike accident even though the accident was not caused by a defect in the bike.

I realize full well that the National Commission on Product Safety in its report which fostered the creation of the CPSC spoke highly of this emergency room approach, but I believe it is time now for the Commission to cut the embilical cord with the National Commission. That which is written by the National Commission should no longer be viewed by CPCS as the moral equivalent of the stone tablets handed to Moses. The House report on the Consumer Product Safety Act makes clear that the Commission has been directed under section 5 of that act "to maintain an injury information clearinghouse to collect, investigate, analyze, and disseminate information relating to the causes and prevention of death, injury, and illness associated with consumer products." The Commission now after 5 years of existence has still not collected reliable data on the causes of accidents. I think that it is about time that they began doing what they were directed to do.

In conclusion, I would strongly urge that a complete moratorium be placed on the sleepwear standard for at least 2 years, during which time the Commission should embark upon several studies in this area. First, they should seek to determine if children's sleepwear which is not fire retardant is really a safety hazard. Second, if they were to find it a safety hazard, they should develop a standard which would allow the maximum number of fabrics possible be utilized without the need for chemical treatment. Third, no chemical should be permitted to be used on sleepwear until it has been fully tested for toxic and allergic reactions as well as carcinogenicity. Fourth, manufacturers should not be required to manufacture all sleepwear to conform to the standard. Those products not manufactured in conformity with the standard should be clearly labeled. By this means, the consumer could once again have freedom of choice. If he wanted to buy all cotton pajamas, then they would be available. He would know, however, that they are not flame resistant.

James M. Collins.

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